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REFORM OF MEDICARE PHYSICIAN PAYMENT POLICIES: IMPACT ON MAGNETIC RESONANCE IMAGING TECHNOLOGY

Lisa I. Iezzoni, M.D., M.S.
Oren Grad, M.D.
Mark A. Moskowitz, M.D.

Health Care Research Unit
Section of General Internal Medicine
Evans Memorial Medical Foundation
Boston University Medical Center

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Lisa I. Iezzoni

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CHAPTER 1

INTRODUCTION

PURPOSE OF THE REPORT

Magnetic resonance imaging (MRI) swept onto the diagnostic imaging scene on a wave of clinical and scientific enthusiasm. But its short lifetime of clinical use has occurred in a climate of the most rigorous fiscal constraints ever levied against the nation's health care system overall. Thus, MRI has fallen into the limbo currently experienced by many other big-ticket technologies, as providers attempt to decide whether these expensive techniques are worth the price in an environment of uncertainty.

MRI is the latest in a long series of advances which have elevated the diagnostic imaging industry to a position of particular preeminence in the United States. Its most famous immediate predecessor -- the computed tomographic (CT) scanner -- was hailed as a "milestone in modern medicine" (Moloney, Rogers, 1979). MRI appeared to equally fervent accolades. MRI is a technique based on the physical response of atomic nuclei to imposition of a forceful external magnetic field. Thus, this imaging modality dispenses with the ionizing radiation required by CT. When meticulously performed, MRI can create images of startling detail; its enthusiasts compare these pictures to the illustrations in anatomy textbooks. Because of its remarkable imaging abilities without the radiation danger, MRI has been touted as a replacement for CT and other standard radiologic technologies.

For a variety of reasons, the avid zeal of MRI supporters has not spread uncontrollably through the medical community. As with other new technologies, the limited clinical experience with MRI has yielded distinctly mixed results. According to Dr. DiChiro of the National Institutes of Health:

> After the frenzied enthusiasm of earlier years, one senses the beginning of a new, more sedate season in the comprehension of magnetic resonance imaging. The exquisite, explicit detail of the images produced with this technique, without the burden of ionizing irradiation, still kindles a justifiable fascination among many physicians. Some diagnostic disappointments and clear debacles, however, are taming the former excessive expectations.
>
> Lack of specificity of certain MRI pathologic findings is being recogized as a limitation equal to, and perhaps more pronounced than, that in computed tomography (DiChiro, 1985, p. 135).

Caution about MRI also has been generated by a generic sense of skapticism about technology overall and the actual utility of diagnostic imaging in particular. Particular concern revolves around the possibility that, in many cases, diagnostic acumen has outstripped therapeutic possibilities: earlier or more precise diagnosis does not necessarily translate into improved outcome for an individual patient.[1] Comparisons with Great Britain have offered some insight into this issue. Americans receive 3.4 times more head CT scans than their British counterparts, and 10 times more body CT scans. But there is not clear evidence that the American scanning practices result in improved patient outcome (Aaron, Schwartz, 1984).

The complicated and changing components of MRI machinery itself have also contributed to a sense of caution:

> There is great uncertainty over the relative advantages and disadvantages of the different types and sizes of MRI magnets, each of which is associated with widely varying clinical claims, purchase prices and siting and operating costs... Hospitals learned from their experiences with CT the costs and risks of obsolescence which result from premature adoption of early models of new technologic equipment. The technical uncertainties surrounding MRI are even greater, as are the costs of errors of premature adoption of technology under the DRG reimbursement system (Schwartz, Hillman, 1985).

Thus, an uncertain reimbursement environment is not the only hurdle confronting the nascent technology of MRI. But payment issues will certainly have an important impact. The purpose of this report is to examine the potential results of modification of one particular component of the payment picture: Medicare payment for physician services. How will changes in the way Medicare pays physicians affect the use, dissemination, and development of MRI? Concern focuses on four broad categories of payment reform:

- modification of the current system;
- fee schedules;
- packaging; and
- capitation.

The speculative nature of this exercise is further compounded by the limited experience with MRI to date. The technology is in an early stage of development -- the stage in which it is moving from scattered pockets of support to adoption by more powerful interest groups such as professional associations and institutional structures (McKinlay, 1981). Virtually all the reports of its clinical utility are anecdotal, based upon small numbers of patients, or founded upon generally unblinded comparisons with other standard diagnostic modalities, usually CT. Almost nothing has been written about its place in the actual medical management of patients. Thus, few inferences can be made about the role of MRI in good quality medical care. MRI clearly has great potential to benefit future patients. But this potential has yet to be realized.

ORGANIZATION OF THE REPORT

The remaining portion of the report is divided into three chapters. The next chapter examines MRI itself, looking at aspects of the technology which particularly affect costs, suggesting the direction of future developments, listing areas of clinical applications, and describing how MRI fits into the current health care system. Because this is a report about payment policy, not MRI itself, only enough MRI background is provided to render the policy discussion intelligible. The last part of Chapter 2 speculates about what will happen to MRI should the current physician reimbursement system remain intact. Chapter 3 proceeds through each of the four physician payment options. For each, it looks at how MRI would be affected in a number of areas. Finally, Chapter 4 suggests the policy implications of the preceding analyses.

FOOTNOTES

1. Early diagnosis may eventually produce better outcomes for future patients if this information is integrated into research protocols targeting therapies.

CHAPTER 2

MAGNETIC RESONANCE IMAGING

MRI TECHNOLOGY: HISTORY AND DESCRIPTION

The Development and Physical Basis of MRI (Steinberg, Cohen, 1984; Schwartz, Hillman, 1985)

The physical phenomenon of nuclear magnetic resonance (NMR) was first characterized almost forty years ago in 1946 by the simultaneous but independent experimental successes of American scientists Felix Bloch and Edward Purcell. Their discoveries prompted development of conventional NMR spectroscopy, a technique used to describe the molecular composition and behavior of chemical compounds. Twenty-five years later, in 1971, Damadian used NMR to demonstrate differences in the behavior of water in malignant and benign tissues, and he suggested that NMR possessed "many of the desirable features of an external probe for the detection of internal cancer" (Damadian, 1971). Lauterbur produced the first two-dimensional NMR image, a cross-sectional portrait of two tubes of water (Lauterbur, 1973). Lauterbur suggested the potential utility of his technique to medical imaging, and soon afterwards multiple researchers began development of clinical NMR imaging systems. The first human whole body NMR scan was accomplished by 1977. Improvements in the scanning process and image quality continue with, as yet, no limits in sight. In this clinical context, NMR techniques have experienced a name change, to the current prevailing appellation, magnetic resonance imaging (MRI).[1]

The current clinical utility of MRI is limited to proton (i.e., hydrogen) imaging, although a plethora of additional uses are under active investigation (see below). Proton imaging non-invasively produces a representation of internal body structures and organs, without exposure to ionizing radiation (x-rays) or conventional radiologic contrast agents. Proton imaging is founded upon a basic physical principle: the nuclei of certain atoms possess an intrinsic angular momentum, or "spin." Because nuclei carry an electrical charge, those that "spin" generate tiny magnetic fields. These magnetic fields can be brought into alignment by the imposition of a forceful external magnetic field. The addition of radiofrequency (RF) energy, at a specific frequency characteristic of the type of nucleus and the strength of the imposed magnetic field, perturbs the alignment of the tiny nuclear magnetic fields. When the RF energy is removed, "relaxation" of the nuclei to their initial state of alignment results in the release of a radiofrequency signal which can be detected by an RF receiver. The measured signal is a function of a number of factors, including the density of the relevant nuclei in the tissues and two "relaxation time" parameters, T_1 and T_2, which are affected by the physiochemical environment of the nuclei being examined. Using this signal information, mathematical algorithms reconstruct an image of the anatomy being examined. Current MRI focuses upon hydrogen, an element with a single proton in its nucleus. Hydrogen is particularly amenable to imaging in biologic systems because it is ubiquitous in organic compounds and of course in water.

Thus, four major components are essential to MRI technology:

- Magnet. The magnet must be both powerful and large enough to completely encircle the structure to be imaged. The absolute strength required of the magnet is a point of considerable contention among various investigators and manufacturers.[2] Current magnets range in field strength from about 0.15 tesla for the resistive air-core type magnet to over 4.5 tesla for a new superconducting magnet prototype.
- Radiofrequency Source. The RF source must be able to provide sufficient energy to deflect the atomic magnetic fields from their parallel orientation.
- Radiofrequency Receiver. The RF receiver must be able to detect the energy released during proton relaxation.
- Computer and Display System. A computer with a large storage capacity and sophisticated array processor

must receive the data and format it into a pictorial display.

These four components of MRI machinery present important implications for costs and location of this technology. These implications are described in the next section.

MRI Machinery

The Magnet

Among current imaging modalities, the use of a magnet is unique to MRI. To the extent that use of the magnet provides a substitute for the dangers of ionizing radiation of existing technologies (e.g., conventional x-rays, CT and nuclear medicine scans), this is a decided benefit of MRI. But as with most benefits, there is a cost: the magnet component generates substantial capital and, in many cases, operating expense and precipitates major concerns about equipment location.

The MRI magnet behaves as does any other magnet. It may produce an external magnetic fringe field or in turn may be influenced by metallic structures in its vicinity. This caused concern about safety on one hand -- "strong magnetic fields may turn ferromagnetic objects into dangerous projectiles" (Kneeland, Lee, Whalen, et al., 1984, p. 44) -- and about image quality on the other hand -- adjacent ferrous metal objects may distort the homogeneity of the magnetic field around the object being imaged.

The size and power of the MRI magnets also prompted two additional concerns: first about the extensive structural support required by the sheer weight of the magnet and second, about the large space needed to cool particular types of magnets. All of these problems have conspired to make MRI siting costs significantly higher than those of conventional imaging techniques (Fed. of Am. Hosp. Rev., 1983, p. 24).

Before discussing approaches adopted for addressing these problems, it is important to emphasize that all magnets are not alike. The number of different magnet types has more than doubled in the last two years, expanding from three types to seven different types (AHA, 1985, p. 41). Magnets can be divided into two broad classes; permanent magnets and electromagnets (Elscint, 1983). The first class, permanent magnets, conform to the standard concept of a magnet -- they are composed of elements which require no external energy source to maintain their strength (White, 1985). These magnets do not produce the stray magnetic fringe fields which create a major siting dilemma for other types of magnets. They have the further advantage of requiring no cooling and no electricity. However, they tend to be extremely heavy (rendering them virtually immobile) and can deliver field strengths no higher than 0.3T. Inhomogeneities in the natural magnetic field may also present problems, which may however be eventually resolved by use of computer algorithms to correct for field distortions (AHA, 1985).

The second class is electromagnets, in which magnetic fields are generated by passsage of an electric current through suitably arranged coils of wire. These magnets can in turn be divided into two groups, resistive and superconducting. Resistive electromagnets are noted for their relatively light weight and low initial cost. However, because of the electrical resistance of the copper or aluminum wire coils, a large power supply is required to maintain the magnetic field and a cooling system (usually cold water) to absorb the heat generated by the coils. A further disadvantage is the relatively low field strength available from resistive systems -- the highest to date being 0.235T. As competing technologies have progressed resistive magnets have lost much of their early popularity.

Currently the most popular type of magnet is the superconductive electromagnet, which uses coils made of special alloys that offer no resistance to current flow when operated at temperatures near absolute zero. Once the desired magnetic field strength is reached, the power supply can be switched off for an indefinite period of time. The necessary cooling is achieved by enclosing the coils in a vessel called a cryostat, which uses liquid helium, liquid nitrogen, vacuum spaces and special insulating materials. The special advantage of superconductive systems is their ability to deliver uniform, stable, high strength magnetic fields. Disadvantages include high cost and the risk of sudden collapse of the magnetic field, called a "quench," due to mechanical or electronic difficulties or operator error. Restarting a system after a quench can take several days and cost tens of thousands of dollars. Furthermore, these magnets produce significant fringe fields and are particularly susceptible to nearby ferrous materials.

From this discussion it is obvious that different magnets offer a range of characteristics along such parameters as magnetic field strength, fringe field strength, weight, cooling requirements, electricity use, and so on. No clearcut trend uniformly supporting one type over another appears, particularly because there is as yet no consensus about perhaps the most crucial parameter -- optimal field strength. Debates over optimal field strength reside in the tenuous realm of prophesy, whether or not spectroscopy and imaging of elements other than hydrogen (e.g., phosphorus) will become a practical reality (see below). Most experts agree that for the current use of proton imaging, low strength magnets are entirely adequate. But for these other potential uses, high strength magnets (at least 1.5 to 2.0T) appear to be desirable. Because of the large cost of the magnet, MRI purchasers have been wary of investing in systems which may potentially become obsolete.

> Considerable uncertainty and confusion has forced many hospitals to race for high-field systems, or buy a superconducting cryogen magnet tank that will accommodate a higher field upgrade at a later date... the upgrade cost is

> likely to be substantial, at least $0.5 to $1 million... (AHA, 1985, p. 39).

However, even this strategy does not remove all risk. It is not yet clear that upgrades of existing equipment will prove suitable for these potential future applications.

Architectural approaches to overcome the problems of magnetic shielding have changed substantially in the last few years. Original structural doctrine emphasized eliminating iron or steel in building design. When iron was used (e.g., in stud supports), architects compensated by increasing the size of the structure to reduce the proximity of the magnet to ferrous materials. Now the pendulum has swung to inclusion of thick steel plating explicitly for magnetic shielding. Steel boxes are fashioned to encompass superconducting magnets. Thus, new MRI facilities can be smaller and closer to other ferrous structures (e.g., elevators, parking lots) than originally expected. But these architectural advances do not appear to have been accompanied by any diminution in siting costs (AHA, 1985).

One footnote to this story may bear important implications for the future use of MRI. Up until very recently these shielding problems were thought to present a virtually insurmountable barrier to development of a mobile MRI unit. "Driving around town with a high magnetic field could cause some serious problems like erasing cassette tapes and credit cards of fellow motorists" (AHA, 1985, p. 58). But mobile systems have been developed using non-superconducting magnets without fringe fields. In addition, new techniques permitting easy de-energizing of magnetic fields in superconducting systems have made these magnets a feasible mobile alternative. Receiving sites where the magnet would be reactivated would require sturdy trailer pads, distance from public roadways, and possibly steel-plated garages. All these requirements tend to push the price of mobile systems well within the range of fixed units. Nevertheless, some manufacturers project that 30 to 40% of the future MRI market will involve mobile units (AHA, 1985).

Radiofrequency Equipment

The magnet is not the only component of the MRI system which requires special architectural consideration. The radiofrequency apparatus also needs protection from such outside interference as radio and television signals, paging systems, lighting and other electricity sources, computer systems, some medical devices, and motor vehicles. A variety of minimal RF shielding approaches have been tried, but most designers continue to recommend complete shielding. The steel plating described above for the magnetic shielding is useful but not sufficient for RF shielding. Every break in the steel (e.g., for air circulation) carries the risk of admitting untoward RF interference. In addition, electrical lines must be carefully shielded. All these considerations add to the costs and complexity of installing MRI equipment.

Computer Component

The software and display components offer the major frontiers for advances in MRI capabilities according to a number of experts. The specifics of currently employed algorithms are too complex to describe in detail in this report. Suffice it to say, that the RF energy received during scanning is elaborately reinterpreted to produce pictorial images of anatomic regions. One of the chief unique assets of these images is that they can be presented in virtually any plane (as opposed to the conventional axial representation of CT scans) and can even be three-dimensional. Finally, as a corollary to the architectural discussions above, in systems with fringe fields, the computer must itself be protected from interference by the magnet and RF components of the MRI machinery.

Current Research (AHA, 1985; Goldman, 1985; Parrot, 1985)

Research in MRI technology is proceeding on a number of frontiers, some aiming towards improving image quality, others directed towards non-imaging applications (e.g., spectroscopy). A number of these research areas are summarized briefly below:

- Proton (hydrogen) imaging. Efforts continue to determine optimal forms for the imposed static and radiofrequency fields and to devise more efficient methods of data collection and refined image reconstruction algorithms. This research is expected to further improve image quality and decrease scanning time.

- T_1/T_2 measurement. Much of the early development of MRI technology in medicine was spurred by the hope that measurements of the T_1 and T_2 parameters could be used to distinguish between normal and abnormal tissues. Results in this area have been somewhat disappointing, however, leading some to question the clinical usefulness of measured T_1 and T_2 values. Nevertheless, work continues on improving accuracy of measurement of T_1 and T_2 and on determining clinical correlations (Kjos, Ehman, Brant-Zawadzki, 1985; Kjos, Ehman, Brant-Zawadzki, et al., 1985).
- Measurement of blood flow. MR images of blood vessels are affected in a complex way by the velocity of blood flow. This discovery has led to efforts to quantify blood flow using magnetic resonance measurements (Singer, Crooks, 1983; Wedeen, Rosen, Chesler, et al., 1985).
- Contrast agents. MRI is highly touted for its ability to generate useful images without the contrast agents common in conventional x-rays and CT scans. Yet, there are a number of areas where MRI performance has

been disappointing to date (e.g., bowels, vasculature), but may be improved by use of contrast agents. MRI contrast candidates (e.g., manganese, gadolinium-DTPA) function by altering the magnetic environment within the body (Strich, Hagan, Gerber, et al., 1985; Gadian, Payne, Bryant, et al., 1985).

- Imaging nuclei other than hydrogen. A number of other elements -- phosphorus, sodium, fluorine and carbon -- are currently being investigated. Phosphorus is the focus of most research efforts because of its importance in basic cellular activities. But the potential utility of each of these elements depends on its biologic behavior in disease; for example, the sodium content of dead or dying cells rises dramatically. Therefore, sodium imaging may be useful in locating dying tissue, as in strokes or heart attacks. This non-hydrogen imaging currently offers three major drawbacks: the need for very powerful magnetic fields, lower resolution images, and prolonged imaging times (Hilal, Maudsley, Ra, et al., 1985; McFarland, Koutcher, Rosen, et al., 1985; Maris, Evans, McLaughlin, et al., 1985).
- Spectroscopy. Conventional NMR spectroscopy has been used to measure chemical compounds involved in basic

cell metabolism. Spectroscopic information is usually presented as a two dimensional graph, in which the peaks along the graph represent specific chemical compounds. "Examining the height of peaks corresponding to different compounds in a family, their relative position with respect to one another, and how these change over time can be used to monitor the progress of a disease" (AHA, 1985, p. 19). The non-invasive measurement of human metabolism offers a tremendous potential to advance clinical science. Spectroscopy, however, demands high field strength systems and is years away from widespread clinical applications.

- Surface coils. Small RF coils that can be placed on the body surface near an organ of interest have been used to obtain conventional NMR spectra. A recent refinement of the technique, "topical magnetic resonance," has improved the accuracy with which the region being measured can be determined. Surface coils are also now being used to collect data for proton MR images, and have demonstrated the potential to yield very high quality images of certain parts of the body (e.g., orbit, knees). The need for a variety of coils, however, may increase the complexity and cost of an MRI installation (Radda, 1983; Edelman, Shoukimas, Stark, et al., 1985; Schenk, Hart, Foster, et al., 1985).

Safety and Patient Acceptance

The absence of ionizing radiation in MRI techniques is considered a prime benefit of this imaging modality. Some have claimed that the MRI process is totally safe. Others, however, are more reluctant to make such categorical assertions: x-ray exposure was itself considered safe until decades after its discovery by Roentgen in 1895. Concern focuses on the potential harmful effects of manipulating the magnetic alignment of atoms in living tissues. Experiments exposing biologic systems to static magnetic fields up to 2T have not yielded any potential harmful effects. Deleterious influences of higher force fields have not yet been adequately studied, but may need to be monitored in the future. Another concern stems from the possibility of body heating due to absorption of RF energy. Elevations in core body temperature by less than 1° C may be safe, but this area also bears further investigation (Budinger, Lauterbur, 1984). Thus, although no side-effects of MRI on body tissues have yet been established, experience with the technique has been too brief for definitive statements about the long-run safety of the technique.

The magnet offers the obvious hazard of attracting adjacent metallic objects and transforming them into moving missiles. Such objects as watches, pens with metal clips, scissors, metal intravenous poles, and surgical instruments are susceptible to the magnetic pull. To guard against these items, many facilities have installed metal detectors at their entrances. The influence of the magnet also precludes imaging patients who are on life-support systems (e.g., respirators) which have metallic components. Metal implants such as vascular clips, shrapnel, prostheses, or some intrauterine devices also are attracted to the powerful magnet. The magnet may exert sufficient torque on these implants to dislodge them, posing a risk of bleeding or tissue damage. Because of these dangers, providers are cautioned not to image patients with metal implants. (Some patients may not be aware of such implants as metal cranial aneurysm clips. Patients uncertain about metal devices need to be screened first by conventional x-rays.) Finally, the electromagnetic signals released by the magnet may precipitate currents in cardiac pacemakers which then cause heart arrhythmias. Because of this, MRI is contraindicated in persons with pacemakers. These patients should also ideally be excluded from areas within the 5 gauss fringe field of the magnet.

Given these specific contraindications, how do most patients fare during MRI scanning? The procedure is non-invasive and, to date, internal contrast materials are not routinely used. Thus, from the patient's perspective, the major drawbacks are: (1) a sense of claustrophobia from being positioned within the fairly narrow aperture of the magnet; and (2) discomfort from prolonged periods of lying still on a hard surface during the imaging procedure. Because of the constraint of the size of the magnet aperture, extremely obese patients may not be suitable candidates for MRI. Patients who are unable to lie still may also be inappropriate. It is estimated that the sensation of claustrophobia may be strong enough to prevent MRI in a few percent of patients (Steinberg, Cohen, 1984).

CLINICAL UTILITY

The Medical Evidence

Reports abound in the recent medical literature describing MRI's ability to scan virtually every anatomic region, from the pancreas to the knee. Many of these provide testimonials of the success of MRI's imaging process itself by publishing the "exquisite images that are helping to fuel excitement about NMR imaging" (Steinberg, Cohen, 1984, p. 31). The apparent anatomic detail and high quality of these MRI pictures has incited considerable respect and enthusiasm for the technique in the general medical community. Thus, casual perusal of this genre of journal report would suggest that the proven ability of MRI to produce superb images serves alone as a sufficient basis for widespread dissemination of the technology.

A more balanced reading of the medical literature engenders a sense of caution. First, with regards to the striking images, looks may in fact be deceiving. Many of these published examples display abnormalities of which the investigators were already aware. Scanning parameters were carefully selected to yield the most photogenic results. But the most beautiful pictures may not provide the appropriate information for detection of specific types of diagnoses. MRI images vary considerably depending on the pulse sequences used during scanning, and certain pulse sequences are better able to detect specific pathologic processes (Posin, Ortendahl, Hylton, et al., 1985). Only by understanding the exact nature of the scanning process can one adequately interpret MRI images. Acquiring such understanding may take from several months to up to a year and a half of training (AHA, 1985). In addition, many of the best images are obtained only by prolonged scanning, with use of multiple pulse sequences in an effort to identify the specific values yielding the clearest pictures. These lengthy imaging times may be impractical for most non-research MRI units.

Second, to date there have been no large-scale, rigorously designed (e.g., prospective, blind, randomized or at least well-controlled) clinical research trials studying the efficacy of MRI or comparing MRI with other diagnostic modalities. Most existing studies report on few patients (typically less than 30) and represent "unblinded" interpretations of MRI scans (i.e., the scan reviewers generally already have perused the patient's history, results of other diagnostic tests including CT, and even the results of pathologic exam of the tissue being studied). A number of investigations currently underway, such as a National Cancer Institute protocol at six medical centers, may ultimately provide more useful data on the relative clinical utility of MRI. "Present medical literature, however, simply does not permit systematic comparison of the sensitivity, specificity, and predictive value of MRI with competing technologies" (Stason, Localio, 1985).

Third, one attractive feature of MRI may actually make its complete evaluation even more problematic: unlike a technology such as lithotripsy which has fairly well-circumscribed clinical indications, MRI may be useful in an extremely broad array of clinical conditions. A study of the efficacy of MRI in detecting cancer may offer only limited insight into its utility for coronary artery disease or for knee injuries. "Unfortunately, because of the diverse clinical applications of MRI and its evolving status, some time will pass before its ultimate role as a diagnostic tool can be established" (Schroeder, 1985). However, the time window during which MRI can be rigorously evaluated (e.g., by prospective, randomized clinical trials) is probably here and may be soon past (Fineberg, 1985). Once MRI becomes part of standard medical practice by virtue of frequent use, it may be considered unethical or immoral to withhold it from patients during a clinical trial. Thus, if MRI is ever to be systematically studied, this research must begin quite soon.

Factors Influencing Clinical Utility

Even though virtually no definitive information on the clinical utility of MRI is yet available, it is possible to speculate about aspects of the technology which may make it useful in specific clinical settings. Such general attributes of MRI include the following:

- Absence of ionizing radiation. This feature makes MRI desirable for settings where one particularly wishes to avoid x-rays: in fetuses for in utero diagnosis,[3] in young children, in adults who have been exposed to excessive radiation, in specific tissues which are susceptible to x-ray damage (e.g., ovaries, testes).
- Bone and Calcification. MRI does not image cortical bone (the hard outer layer) or lesions with calcium deposits (e.g., atherosclerotic plaques, certain tumors). This means that MRI will not be useful for defining these structures. Conversely, MRI does not produce the distortions of the image caused when bone

interferes with conventional x-rays. Absence of this troublesome "bony artifact" is of great significance: MRI is able to adequately image areas which were previously virtually inaccessible, for example, the posterior fossa region of the skull and the cervical spine. MRI may also be extremely helpful for other regions surrounded by bone (e.g., bone marrow spaces, pelvis, joints).

- Magnetism. As mentioned above, patients with internal ferromagnetic implants and cardiac pacemakers should not be imaged. However, patients with non-magnetic metallic clips and implants are not affected, and MRI images these patients without the distortions caused by interference of these implants with regular x-rays (Mechlin, Thickman, Kressel, et al., 1984). The magnetism unfortunately precludes the use of MRI with ferromagnetic surgical instruments. In recent years, a growing application of CT and ultrasound has been in guidance of biopsies and other internal procedures. MRI cannot be used for this purpose unless suitable non-magnetic instruments can be developed.
- Long Scanning Times. Several minutes of scanning may be required to obtain signals adequate for image reconstruction. This creates a problem for scanning

of organs which are in constant motion (e.g., heart, lungs, intestine). A technique called "gating" has been developed to reduce motion artifact for heart scanning: the image is coordinated with the electrocardiogram (Higgins, Hricak, Gamsu, et al., 1983). However, abdominal studies continue to be compromised by respiratory motion and peristalsis. Some of these problems may be partially addressed by the advent of machines with faster scanning times.

- Absence of conventional intravenous contrast material. Most conventional contrasts used in urography and angiography are iodine-based compounds which have a number of important albeit rare side effects (e.g., anaphylactic shock which is potentially lethal, acute renal failure). The side effects are relatively more common in patients who have had previous dye reactions, patients with allergies or asthma, and patients with certain chronic diseases such as diabetes and multiple myeloma (Emmerson,1982). These patients would obviously benefit from the absence of contrast.
- Dependence on Hydrogen. Processes which increase the water content of tissue are particularly highlighted by proton MR imaging. These processes include

infarcts, primary and metastatic tumors, abscesses, hemorrhage, and demyelination (Bradley, 1984). One of the most striking aspects of MRI is its ability to differentiate white and gray matter in the brain, an ability related to the 14 percent difference in water content between these two tissue types (Smith, 1983). Lungs are difficult to image because of low proton density.

- $\underline{T_1/T_2}$. Tissue differentiation is afforded not only by water content but also by variations in the two relaxation parameters, T_1 and T_2. For example, T_1 is prolonged in malignant tumors and in inflamed tissue (Smith, 1983). As understanding grows of T_1/T_2 correlations with specific pathologic processes, MRI could become valuable in an extremely broad set of clinical situations.
- Spatial Resolution. MRI's spatial resolution is "slightly reduced" when compared to CT (Hendee, Morgan, 1984). However, this factor is considered of different import depending on the author and clinical application. Some feel that the tissue discrimination prowess of MRI "more than compensates" for its inferior spatial resolution (Hendee). Others prefer CT in certain settings (e.g., small lung tumors)

because of its superior spatial resolution (Baker, Berquist, Kispert, et al., 1985). New surface coil technology may improve spatial resolution (Paushter, Modic, Borkowski, et al., 1984).

- Multiple imaging planes. MRI can present its image in virtually any plane -- axial, coronal, sagittal -- as opposed to the conventional axial representation of CT. This ability renders MRI useful in settings where anatomic relationships are particularly important. For example, these multiplanar images are helpful in assessing traumatic damage to tendons, ligaments, and muscles, and in the central nervous system, sagittal views aid evaluation of the brainstem and cervical spinal cord whereas coronal images enhance visualization of the temporal lobes (Baker, Berquist, Kispert, et al., 1985).
- Blood Imaging. Flowing blood produces a complex signal which does not yield an adequate static image but may allow velocity measurement. Thus, the walls of vessels and the heart appear in stark natural contrast against their blood-filled cavities. This may be advantageous, allowing study of the inner surface of the vascular wall and the innermost structures of the heart. However, MRI is less able

than CT to identify fresh, stationary blood, as in an acute cerebral hemorrhage.

Current Clinical Applications

Current clinical applications of MRI flow from those general features of the technology outlined above. Table 2-1 briefly describes a number of areas where MRI may prove useful; this list is meant to be illustrative, not exhaustive. This table also lists other diagnostic modalities which may be viewed as competing with MRI. From these data, one can draw several general conclusions.

First, MRI holds tremendous potential not only to advance diagnostic science, but also to replace other modalities which carry quantifiable risks. However, at this stage, "potential" is all there is. Much more work is needed to clearly demonstrate the basic abilities of MRI before one can begin to contemplate the superiority of MRI over other techniques.

Second, certain anatomic areas have never been adequately imaged by conventional modalities. Two of these -- the posterior fossa and cervical spine -- are nicely revealed by MRI. Therefore, MRI has become the modality of choice for scans in these regions. The pelvis also appears a fruitful site for MR imaging, and the absence of ionizing radiation is of particular import for this area. But more study of pelvic scanning is

Table 2-1.
(1 of 3)

Anatomic Region	Clinical Application	Competing Technology	Comments
Brain: Posterior Fossa	Because of the absence of bone-induced distortions, MRI has proven uniquely capable for imaging the posterior fossa region -- the cerebellum and brain stem. Examples of lesions detected in this area include infarction, primary brain and metastatic tumors, cysts, and vascular malformations.	MRI surpasses CT plus metrizamide contrast and myelography for the posterior fossa region.	Posterior fossa imaging is one area in which there is general agreement: MRI's superiority is clearcut.
Brain: White Versus Gray Matter	Because of its ability to discriminate white and gray matter, MRI is considered useful in evaluation of demyelinating diseases, such as multiple sclerosis (MS). Not only does MRI identify MS plaques, but also repeated scans can demonstrate changes in the plaques over time. However, MRI has been tested mainly in patients with very advanced disease.	CT does not perform well in detecting MS lesions. Thus, in the past, diagnosis of MS has been based upon a number of non-imaging factors: classic history and physical exam, findings in spinal fluid, evoked potential tests, etc.	Although MS is an uncommon disease, its symptoms can be very non-specific (e.g., fatigue). Scanning every patient with such symptoms, could open a floodgate of demand for MRI scans. MS is almost never diagnosed de novo in the elderly.
Brain: Above Posterior Fossa	In the region of the brain above the posterior fossa, MRI has imaged infarctions, tumors, aneurysms, infections, hemorrhage, and hydrocephalus. Since most of these processes increase the water content of the brain tissue, certain findings may be difficult to interpret: for example, differentiating brain tumors from cerebral edema.	The most obvious competing technology is CT. However, clear-cut and uniform superiority of one imaging modality over another has not yet been proven. MRI may be better in one type of diagnosis while CT is better in another. Authors disagree on specific issues. For example, one researcher may feel that MRI is more sensitive than CT at detecting small tumors (Bradley, 1984) while another may disagree, (Han, Bonstelle, Kaufman, et al., 1984; Stason, Localio, 1985). MRI also competes with cerebrovascular angiography and radionuclide scans.	Information is not yet available to clearly favor MRI or CT in all situations. Thus, in ordering a scan, a clinician must have a reasonable clinical sense of what he expects to find in order to select the best modality. For example, if a calcified structure is anticipated, CT is the better choice. In situations where clinical expectations are limited, physicians may order both tests to cover all possible scenarios.

Anatomic Region	Clinical Application	Competing Technology	Comments
Spinal Column	MRI has been useful in detecting such rare but debilitating processes as spinal cord cysts, tumors, and cavitary lesions. Because of the absence of boney artifact, lesions in the cervical spine are clearly imaged. MRI may be the most sensitive imaging modality for identifying degenerative disc disease (Modic, Pavlicek, Weinstein, et al., 1984). But the specificity of this usage is problematic: more than half of middle-aged subjects demonstrate disc abnormalities on MRI but are asymptomatic.	Contrast-enhanced CT and myelography are the chief competing technologies. Both are invasive in the sense of requiring potentially harmful contrast materials. But whether they will be dislodged by MRI for spinal column imaging apart from the cervical spine is as yet unknown; further research is required. Conventional spine x-ray films will continue to be important because MRI does not image the calcification which is often a component of back pain etiology.	There is general consensus that MRI is the preferred modality for cervical spine imaging. Apart from that, many of the spinal cord processes for which MRI is potentially helpful (e.g., syringomyelia) are relatively rare conditions. Where demand for MRI could burgeon is in evaluation of degenerative disc disease or back pain. What to do with the information on discs obtained through MRI is not yet clear.
Lungs	Lung imaging has been plagued by several problems: low proton density, chest wall motion, poor spatial resolution.	MRI does not perform as well as CT in lung imaging.	Technologic advances in MRI could overcome some of these impediments in the future.
Heart	In order to obtain useful cardiac images, electrocardiogram gating techniques are required. A natural sharp contrast is provided by the moving blood, thus permitting clear delineation of structures within the heart chambers as well as the valves. Gating has also allowed visualization of portions of the coronary arteries. MRI demonstrates the wall thinning caused by old heart attacks and changes in the sac containing the heart. However, identification of fresh infarcts is still in the research stages (Higgins, Kaufman, Crooks, 1985).	Multiple technologies compete in the area of cardiac diagnosis: CT, echocardiography, radionuclide scans, and angiography. It is much too soon to predict whether MRI will replace or complement any of these technologies.	Advances in MRI technology are clearly needed to enhance MRI's performance in cardiac imaging. Better gating techniques and spatial resolution are of particular concern.

Table 2-1
(3 of 3)

Anatomical Region	Clinical Application	Competing Technology	Comments
Abdomen	Abdominal imaging suffers from motion artifact; respiratory gating may be helpful. MRI images liver tumors, cirrhotic changes, vascular lesions, and cysts, perhaps better than CT. Its utility in gallbladder imaging is hampered by its inability to detect calcification. The pancreas, an organ notoriously difficult to image using conventional modalities, also presents major impediments to MRI imaging. Pancreatic MRI is limited by inability to differentiate anatomic structures and insensitivity to calcification. Nonetheless, some feel that MRI is superior to other techniques in imaging the pancreas. MRI of the intestines has not yet been successful, due in part to the unpredictable motion of peristalsis.	It is very unlikely that conventional intestinal and gallbladder diagnostic technologies will soon be supplanted by MRI. But such modalities as CT, ultrasound, radionuclide scans, and angiography may compete with MRI in other abdominal organs. To date, no large-scale research results support one technique over another.	The choice of appropriate diagnostic modality must be viewed in the clinical context. For example, if one wishes to identify the calcification of chronic pancreatitis, MRI would not be an appropriate choice (see Comments above under "Brain").
Genito-Urinary System	MRI is able to characterize the soft tissue changes which arise in renal disease; it is useful for monitoring transplanted kidneys. Experience with identification of renal tumors is limited. MRI cannot identify calcification in renal masses. MR imaging of pelvic organs is enhanced by the natural contrasts of the tissues (e.g., pelvic fat, urine in the bladder). Because of this and the absence of artifact from pelvic bones, MRI has been useful in evaluating tumors and metastases in the pelvis.	MRI does not use intravenous contrast or ionizing radiation. This a priori makes it potentially more desirable than an important competitor, intravenous urography. CT and ultrasound are also competing technologies. Preliminary results appear to favor MRI in most instances, but further research is needed.	The absence of ionizing radiation may make MRI an important modality for evaluating pelvic disease in women of child-bearing age.

required. The pancreas, which has managed to elude other imaging techniques, may be at least partially captured by MRI, although some major problems remain. These regions which have not been optimally imaged by other modalities form a class of special indications for MRI (Medical Letter, 1985).

Third, in a given organ system, MRI may not be equally capable of detecting all types of pathologic processes. The most obvious shortfall of MRI is in identifying diseases involving calcification of tissues or very small lesions in certain areas. Other more subtle difficulties are problems differentiating certain tumors from edema. In describing these problems, most authors offer a comparison with CT. Aggregating the limited research findings, one can develop lists for given organ systems of diseases in which MRI is superior to, equal to, or inferior to CT. These lists are obviously subject to change as technology advances and more research occurs. However, at this time, these circumstances raise the following caveat: unless he reads the literature widely and discriminately, a general practicing physician may not know which of the two tests, MRI or CT, is preferable in his patient. Even specialists may be confused by the flurry of largely anecdotal reports on different specific indications for MRI. In addition, unless the physician knows specifically what to expect in the scan (e.g., tumor calcification), he may feel more comfortable ordering both tests to cover all possibilities and reduce uncertainty (Allman, Steinberg, Keruly, et al., 1985; Reuben, 1984). This scenario suggests that, in the near future for the majority of cases, MRI will be viewed as a complement for, not a substitute of, CT.

Fourth, CT is not the only technology which should be compared with MRI (Murphy, 1984). In fact, CT provides only a small fraction of diagnostic imaging, and a number of invasive procedures should also be compared. Other technologies which may be contrasted with MRI include: conventional x-rays, ultrasound, echocardiography, radionuclide scans, myelography, mammography, and angiography. However, not enough is yet known to permit definitive comparisons between MRI and these other modalities.

Fifth, there is the potential for use of MRI to skyrocket. Certainly, if the enthusiasm of researchers is infectious, MRI could become one of the most commonly employed imaging techniques. For example, one research group suggested that, "overall, MR appears to be the method of choice for initial screening of suspected brain disease" (Brant-Zawadzki, Norman, Newton, et al., 1984, p. 75). MRI's unique and well-documented ability to delineate the plaques of multiple sclerosis (MS) may make the technique sought after by thousands of patients with non-specific complaints (e.g., fatigue, tingling in an extremity). However, because of the comparative rarity of MS, thousands of scans may be performed to detect only a handful of cases. The central nervous system has been the most heavily explored area to date and thus offers the clearest scenarios for extensive MRI use. However, as MR technology improves in the fields of cardiac and tumor imaging (as is expected), the potential for widespread applicability in a Medicare population grows.

Finally, this issue of clinical applicability is inextricably linked with that of clinical utility and the contribution of MRI to quality of care. These concerns are discussed in the next section.

MRI and Quality of Care

Judging the impact of MRI on quality of care is fraught with several major difficulties. The first and perhaps largest hurdle is the lack of information on the way MRI is currently used in the clinical management of patients. Second, because of the plethora of widely divergent clinical applications of MRI, quality of care must be considered separately for each clinical scenario. Finally, there is a question generic to quality of care discussions across all technologies: by what standards does one measure impact on quality of care? This question is particularly relevant for MRI, because, in many cases, this technology appears to present a classic case of diagnostic methods outstripping therapeutic options.

The case of MS once again proves illustrative. MRI is better able to identify the lesions of MS than any other current imaging modality. Use of MRI may spare the patient an extensive battery of costly, uncomfortable tests (e.g., lumbar puncture, evoked potentials, CT with and without intravenous contrast) which may not yield a definitive diagnosis. However, there is as yet no proven effective approach to palliate or cure the disease. Obtaining a definitive diagnosis of MS may be a desirable outcome in itself. But given current therapeutic limitations, it is unlikely that the course of a patient's illness will be changed. Therefore, the use of MRI to monitor the progress of diagnosed MS is open to debate. Patient preference may play a major role in these considerations: some patients may prefer to know the number and distribution of their plaques; others may not. In the present therapeutic environment, adequate information for clinical management of MS is probably provided by a complete history and physical exam.

However, new diagnosis of MS is exceedingly rare in an elderly population. Cerebrovascular disease and stroke are more pertinent examples for this group. Cerebellar and brainstem infarctions, by virtue of their location in the posterior fossa, offer an indication for MR imaging. But apart from standard supportive measures, there is little that can currently be done to alter the prognosis for most of these patients. Ironically, in one area where there may be therapeutic options, CT is still considered superior to MRI: in acute infarctions, CT is better able to differentiate hemorrhagic from non-hemorrhagic strokes. However, even the therapies suggested by this distinction have not been conclusively proven to be effective (Mohr, Kase, Adams, 1983).

The examples of MS and stroke suggest that use of MRI did not affect patient outcome and thus failed to improve quality of care. There are objections to focusing solely on outcome: this ignores the fact that over the history of medical science, diagnostic modalities have generally antedated therapy by even centuries of time (Holgate, Wortzman, 1978); and also neglects other aspects of quality, such as patient perceptions and evaluations of the structure and process of care. In addition, improving knowledge about disease itself may ultimately lead to important research discoveries which may in the long run improve quality of care. In rigorous research settings, use of MRI specifically to characterize diseases or to monitor response to experimental treatments may be extremely desirable. Such applications of MRI should, however, be handled as investigational and not transformed into widespread clinical practice.

In summary, the value of MRI in terms of altering therapeutic approach and improving quality of care has not yet been adequately studied. Extrapolating only from the MS and stroke examples in which therapeutic successes have been limited may not be entirely fair. MRI has the potential to be useful in certain diseases in which treatments have been more successful, for example, in early diagnosis of some tumors. In addition, research on therapies will hopefully produce new treatments for some of these conditions in which diagnostic acumen surpasses therapeutic skill. Given this dynamic process and the current dearth of information, it is difficult to ascribe an appropriate position for MRI in provision of good quality medical care.

CURRENT USE OF MRI

Diffusion of MRI

The first clinical placements of MR scanners occurred in the United Kingdom in 1978, when Picker International installed 0.15T resistive whole body scanners at the University of Nottingham Hospital and at its own HIRST Research Center in London. The third installation did not follow until late 1980, when FONAR Corporation placed a 0.04T permanent whole body system in Cleveland.

Additional units soon followed, as the diffusion of MRI gathered momentum. The tenth MR unit was in place by early 1982; by the end of 1982, more than 20 units had been installed, and by the end of 1983 more than 70 units were in place (Steinberg, Cohen, 1984). Acceleration continued through 1984, with Steinberg and Cohen (1984) estimating 145 clinical placements worldwide, including 93 in the United States as of August, 1984. A detailed survey by Hillman and Schwartz (Adoption, 1985) identified 151 MRI units in the United States at the end of 1984, including 102 fully operational units and 49 units undergoing installation. The AHA (1985) counted 243 installations worldwide as of early 1985, including 176 in the United States. The American College of Radiology (ACR, MR Site List, 1985; Braden, 1985) reported approximately 200 American MR installations in May, 1985. At the time this report was being written in August, 1985, there were a number of indications that the pace of MRI diffusion is slackening somewhat, although detailed corroborative data are not yet available. Conversations with sources in the MR industry, the hospital sector, and the financial markets suggested a significant slowing of MRI purchase commitments by mid-1985, though it should be noted that more optimistic assessments were encountered as well.

Clearly, the diffusion of MR scanners has been slower than that of CT scanners in the mid-1970's. CT scanners first appeared in the United States in significant numbers in 1974. Five hundred operational CT scanners were in place in the United States by early 1977. The rate of diffusion of CT scanners fell noticeably beginning in 1978; nevertheless, by May, 1980 there were nearly 1500 CT scanners in the United States (U.S. Cong., OTA, 1981). By comparison, there are about 200 MR installations in the United States after four and a half years of diffusion, with some indications that the peak of activity may have been passed by mid-1985.

One early investment analysis projected rapid growth in MRI sales, with a significant fraction of growth earned at the expense of CT sales. More recent projections have been scaled down considerably (see Table 2-2). MR is still generally believed to be competing with CT, though both MR and CT, as well as all other diagnostic imaging modalities, have been affected by the current slowdown in the diagnostic imaging industry overall (Steinberg, Cohen, 1984; Goldsmith, 1984; Goldsmith, 1985).

TABLE 2-2

PROJECTED WORLDWIDE MRI SALES

($ in millions)

	1985	1986	1987	1988
Eberstadt (5/83)	650	1,100	1,750	2,500
Elscint (11/84)	250	300	450	750

Sources: Data from F. Eberstadt & Co. projections reported in Steinberg and Cohen (1984, p. 58)

Data from Elscint, Ltd. projections reported in Goldsmith (1984).

Placement of MRI Units

Examination of the AHA listing of operational and planned MR installations as of early 1985 (AHA, 1985) indicates that the six states with the highest numbers of MR installations are California, New York, Texas, Florida, Pennsylvania and Illinois. The same six states headed the list in a 1980 survey of CT installations (U.S. Cong., OTA, 1981). Each of the 15 largest metropolitan statistical areas (MSAs) in the United States had at least one MRI unit by the end of 1984, and all but two of the 25 largest MSAs had MRI units. The top 50 and 100 MSAs respectively contained 80 and 87 percent of the MRI installations (Hillman and Schwartz, 1985, Diffusion).

Of the 151 MRI scanners identified by Hillman and Schwartz (1985, Adoption), 79 (52 percent) were hospital-based (defined as lying within a hospital complex and having formal organizational ties with it) and 72 (48 percent) were non-hospital based. Most of the hospital-based units were owned by individual hospitals (78 percent) or by partnerships involving a hospital and its university, medical school or non-profit foundation (9 percent). Hospital consortia accounted for 4 percent, while the remaining units represented a variety of unique ownership arrangements. Academic institutions (defined as hospitals having a primary affiliation with a medical school or having their own residency training program in diagnostic radiology) owned 85 percent of hospital-based scanners. Almost one half (47 percent) of the non-hospital MRI units were owned by groups of physician investors. Non-physician investors and joint physician/non-physician investor groups owned 22 percent, while several proprietary corporations, either alone or jointly with private investors, owned 10 percent. Universities, medical schools, hospitals and other non-profit foundations accounted for the remainder of non-hospital based scanners (Hillman and Schwartz, 1985, Diffusion).

These figures can be contrasted with the distribution of CT scanners as of May 1980: 78 percent were in hospitals, 1.4 percent were mobile units, and 19.9 percent were located in private offices and clinics (U.S. Cong., OTA, 1981). As shown by this comparison, proportionately more MRI installations are located outside hospitals (about 48 percent compared to 20 percent).

Factors Affecting Diffusion and Placement of MRI

State Health Planning Activities

The expense of MR scanners makes them subject to approval by those state certificate of need (CON) programs which continue to monitor large-ticket items. State regulatory activities concerning MRI vary widely, ranging from virtually no constraint (e.g., California, Texas, Minnesota) to strict limitations on the number of installations approved combined with a data collection system to govern future decisions (New York). Because of the absence of data on clinical efficacy and cost-effectiveness, those states that have adopted guidelines regarding new MRI installations have done so on an arbitrary basis. The arbitrary nature of these guidelines has led to much heated dispute and, in some cases, to court action. For example, Massachusetts approved a demonstration project for the period of May, 1984 through May, 1986 which allowed eight MRI units: four in the Boston area and another four located elsewhere throughout the state. The four Boston institutions were immediately selected, but the state CON office has received an additional 15 applications, including many from institutions in Boston. Considerable controversy around this issue is assured. Maine requires that any public or private group, including non-hospital groups, wishing to purchase an MRI unit must complete the CON process. However, two independent radiology groups have taken their case to court, seeking to overturn the current regulations. Data compiled by the federal government (U.S. DHHS, Office of Health Planning, 1984) indicate that, of 168 CON applications for MRI occurring between April 1983 and April 1984, 65 were approved, 27 disapproved, 71 remained pending, 3 were declared exempt and 2 deferred.

The actual impact of these CON regulations on the diffusion and placement of MR scanners is difficult to determine. The available data (albeit limited) together with opinions expressed by individuals involved with MRI in a variety of ways suggest that the CON process has not had a major impact on the overall diffusion of MR. In some cases, however, the plans of specific hospitals for the acquisition of MR equipment have been affected, and a variety of incentives created by the details of the CON process itself and its regulatory scope have affected the specific distribution of scanners. For example, some hospitals acquired investigational devices fairly early, building fully operational MRI centers before state regulatory agencies had the opportunity to establish a policy on MR. In most states, private groups are exempted from restrictions on large capital purchases. Hospitals in these states can gain access to MR services via free-standing installations. OTA offerred a similar interpretation of the first seven years of CT diffusion (U.S. Cong., OTA 1981): broad market forces dictated the overall numbers of CT scanners, while the CON process caused distributional shifts. Some of these results were counterproductive to the goals motivating the CON process in the first place.

Food and Drug Administration (FDA)

The details of the regulation of MRI as a new medical device under the Food, Drug and Cosmetic Act have been extensively reported elsewhere (Steinberg, Cohen, 1984). Suffice it to note that, as "Class III" devices, MR scanners cannot be marketed (in particular, they cannot be promoted or sold at a price greater than cost) until they receive premarket approval (PMA) from the FDA.[4] The FDA first granted PMA for MRI devices in March 1984. As of May 1985, Technicare, Diasonics, Fonar, Siemens and General Electric had received PMA for a variety of whole body scanners, while Picker had received approval for a head unit, leaving Philips and Elscint as the only major manufacturers lacking PMA. Both companies indicate that PMA is expected "soon" (Parrot, 1985; Goldman, 1985).

The majority of MRI manufacturers have stated that the PMA process has had little effect on the aggregate diffusion of MRI because it essentially coincided with research and development activities which were a necessary preliminary to full-scale production and marketing (Steinberg, Cohen, 1984). Those manufacturers whose PMA had come most recently or not at all by June 1985 denied any serious competitive disadvantage. It is not clear whether this will continue to be true for the remaining two major manufacturers should they experience significant delays in obtaining PMA: many purchase contracts are contingent on the receipt of PMA.

The Reimbursement Environment

Uncertain reimbursement appears to be the most significant constraint on diffusion of MRI (AHA, 1985; Goldsmith, 1984; Goldsmith, 1985; Deffebach, Moorefield, 1983; Elscint, Ltd., 1984;

Diasonics, Inc., 1985; Rollo, 1985; Schwartz, Hillman, 1985). The introduction of Medicare's DRG-based prospective payment system, together with uncertainty about the method which will be selected for determining capital expenditure reimbursement under Medicare, has had a significant adverse impact on the diagnostic imaging industry as a whole. Hospitals have been forced to restructure their operations in response to a variety of actual and potential new financial constraints.

The pressure on hospitals has fueled a trend toward establishment of free-standing imaging centers by physician groups and private companies, a trend that is clearly reflected in the various MR site listings. However, free-standing centers are beginning to confront severe reimbursement uncertainties as well. Despite favorable early responses by many commercial insurers and a few Blue Cross/Blue Shield plans, a definitive long-term policy on MR reimbursement remains to be determined by most private-sector insurers. In addition, the Health Care Financing Administration (HCFA) is examining a number of alternative ways of restructuring physician payment under Medicare; several of the alternatives could subject physicians and free-standing centers to many of the constraints and incentives that hospitals now face. It is not yet clear whether the trend toward free-standing imaging facilities will persist, or whether it represents a transient response to an unusual but temporary situation. The effects of the reimbursement environment on MRI are discussed in greater detail below.

Financial Aspects of MRI Use

Costs

Detailed information on the cost of operating an MRI unit is not yet available. Until recently, all cost data published in the literature have been estimates derived via aggregation of plausible estimates for the costs of component parts of a functioning MRI installation. Stason and Localio (1985) analyzed a number of published cost estimates and generated a series of estimates representative of the range of projections encountered in the literature (see Tables 2-3 and 2-4). Recently the results of a survey of operating MRI units have been reported (Evens, Jost, Evens, 1985; see Tables 2-5 and 2-6). Although not directly comparable to the Stason and Localio estimates because of differences in the way the data are aggregated and reported, the survey results appear consistent with the theoretical estimates. MRI costs are largely weighted by the high fixed capital and operating costs of an installation; variable operating costs contribute only a small fraction of total MRI costs. Accordingly, the cost per MR scan is critically dependent on numbers of patients scanned.

TABLE 2-3

ESTIMATED COSTS OF OPERATING MRI INSTALLATIONS USING FOUR DIFFERENT TYPES OF MAGNETS

Capital Costs	Permanent	Resistive	0.5 T Superconductive	1.5 T Superconductive
Equipment[a]	$1,525,000	$1,066,667	$1,550,000	$1,766,000
Site Preparation[b]	$ 183,000	$ 353,000	$ 503,333	$ 621,442
Total Capital Costs	$1,708,000	$1,419,667	$2,053,333	$2,387,442
Annualized Capital Costs				
At 7% Interest	$ 379,827	$ 288,892	$ 418,844	$ 482,170
At 13% Interest	$ 482,307	$ 374,072	$ 542,044	$ 625,416
Fixed Costs Single Shift				
Direct-Personnel	$ 146,292	$ 146,292	$ 146,292	$ 146,292
Direct-Electricity	$ 10,067	$ 38,500	$ 6,000	$ 6,097
Direct-Cryogens	$ 0	$ 0	$ 40,400	$ 41,333
Direct-Maintenance Contract	$ 70,667	$ 68,000	$ 108,000	$ 125,000
Direct-Insurance	$ 9,400	$ 9,400	$ 14,667	$ 14,667
Indirect	$ 84,833	$ 100,000	$ 134,850	$ 150,000
Annual Fixed Operating Costs	$ 321,259	$ 362,192	$ 450,209	$ 483,389
Total Annualized Fixed Costs				
At 7% Interest	$ 701,086	$ 651,084	$ 869,053	$ 965,559
At 13% Interest	$ 803,566	$ 736,264	$ 992,253	$1,108,805
Variable Costs	$ 20/scan	$ 20/scan	$ 20/scan	$ 20/scan

a Assumed useful life, 6 years.
b Assumed useful life, 30 years.

Source: Stason and Localio, 1985, pp. 52-54.

TABLE 2-4

ESTIMATED COST PER MRI SCAN FOR FOUR DIFFERENT TYPES OF MAGNETS: SINGLE SHIFT, 7% OR 13% INTEREST ON ANNUALIZED CAPITAL COSTS[a]

	Permanent		Resistive		0.5 T Superconductive		1.5 T Superconductiv	
Scans Per Day	7%	13%	7%	13%	7%	13%	7%	13%
5	$580	$665	$540	$610	$715	$815	$790	$905
10	$300	$340	$280	$315	$370	$415	$405	$465
15	$205	$235	$195	$215	$250	$285	$275	$315

a Calculated from Table 2-3 on the basis of 250 operational days per year.

TABLE 2-5

MRI COSTS REPORTED BY OPERATIONAL INSTALLATIONS

	Mean	SD	Range
Equipment cost	$1,362,000	$ 284,000	$750,000 - $1,900,000
Construction cost	$ 383,000	$ 228,000	$100,000 - $ 900,000
Variable cost/study	$ 27	$ 18	$ 5 - $ 75
Cryogen cost/month	$ 2,145		$ 1,000 - $ 3,500
Electricity cost/month[a]	$ 1,872		
Annual equipment maintenance	$ 98,000	$ 33,000	$ 0 - $ 150,000

Comparisons by Setting	Hospital	Outpatient
Cost of MRI unit	$1,300,000	$1,400,000
Cost of building or remodel	$ 391,000	$ 375,000
Variable cost/exam	$ 29.30	$ 24.60

By Magnet Size	< 0.3T	0.3T - 0.6T	> 1.0T
Cost of unit	$ 868,000	$1,467,000	$1,625,000
Annual equipment maintenance	$ 76,000	$ 100,000	$ 125,000
Variable cost/exam	$ 16.30	$ 28.20	$ 35.20
Cryogen cost/month		$ 2,082	$ 2,950

[a] For seven reporting nonsuperconductive magnets.

Source: Evens, Jost, and Evens, 1985.

TABLE 2-6

ESTIMATED ANNUAL TECHNICAL OPERATING COSTS BASED ON SURVEY OF OPERATIONAL MRI INSTALLATIONS

Fixed costs		
Equipment depreciation[a]		$ 272,000
Building depreciation[b]		$ 21,000
Personnel (nonphysician)		$ 89,000
Equipment maintenance		$ 98,000
Cryogens		$ 26,000
	Subtotal	$ 506,000
Variable costs[c]		$ 54,000
Indirect costs		$ 106,500
Capital costs[d]		$ 175,000
	Total	$ 841,500

a 5 year straight line.

b 18 year straight line.

c Assume 2000 procedures/year.

d Assume 10 percent interest.

Source: Evens, Jost, and Evens, 1985.

TABLE 2-7

MRI CHARGES REPORTED BY OPERATIONAL INSTALLATIONS

Head	Mean	SD	Range
Technical	$ 495	$ 107	$ 204 - $ 700
Professional	$ 163	$ 61	$ 32 - $ 326
Total	$ 652	$ 112	$ 360 - $ 932
Body			
Technical	$ 516	$ 176	$ 227 - $ 1,255
Professional	$ 184	$ 97	$ 32 - $ 364
Total	$ 702	$ 188	$ 360 - $ 1,413

Comparisons by Setting		Hospital	Outpatient
Head:	exams charged/month	59	87
	typical total charge	$ 583	$ 660
Body:	exams charged/month	14	34
	typical total charge	$ 657	$ 679

By Magnet Size		< 0.3T	0.3T - 0.6T	> 1.0T
Head:	exams charged/month	61	89	38
	typical total charge	$ 514	$ 655	$ 617
Body:	exams charged/month	23	28	24
	typical total charge	$ 525	$ 680	$ 617

Source: Evens, Jost, and Evens, 1985.

Charges

Evens, Jost, and Evens (1985) discovered a wide range of charges for MRI scans (see Table 2-7). Outpatient facilities actually had higher charges than inpatient facilities. Our survey of a number of operating MR installations (see Appendix A) revealed actual total charges for an MR scan (technical fee plus physician fee) ranging from a low of $450 to a high of $1000. Many centers reported a range of charges corresponding to the complexity and duration of different types of scans. Some centers indicated that their charges were affected by competition with other providers, although this response was associated with both unusually low and unusually high charges. The split of the total fee between technical and physician components varied as well, with figures quoted ranging from 65 percent/35 percent to 80 percent/20 percent (technical/physician). Some centers reported no predetermined ratio, preferring instead to adjust the proportions on a regular basis according to current financial conditions.

Respondents to the Evens, Jost, and Evens survey estimated a revenue reduction factor for partial-pay patients and bad debts of 40 percent because several large third-party payors were not reimbursing for MRI at the time of the survey (late 1984 - early 1985). The respondents anticipated a 16 percent reduction factor when all major payors approve reimbursement. Based on the 40 percent factor, Evens, Jost and Evens (1985) estimated that the "typical" MRI installation was operating at a substantial loss. Outpatient facilities were projected to be closer to breaking even than inpatient facilities because of their higher charges and greater volumes.

Reimbursement Policies of Major Third-Party Payors

A January, 1985 survey of the 30 largest commercial insurers conducted by Mobile Technology, Inc., indicated that 11 generally pay for MR, 13 review claims on a case-by-case basis, 4 had not yet determined a reimbursement policy, and 2 generally did not accept MR charges. A positive response on the survey, however, does not necessarily indicate that an insurer has received a significant number of MR claims (Ford, 1985). Many insurers are learning about MRI only as they accumulate their first MRI claims. Adverse experience, a restrictive payment decision by HCFA, and/or a restrictive recommendation by the Blue Cross and Blue Shield Association (BC/BSA) could result in a modification of the current favorable policy of many private insurers toward MRI coverage.

Individual Blue Cross/Blue Shield plans reserve the right to make their own coverage decisions, and our provider survey indicates that BC/BS policies vary considerably from region to region. Reported BC/BS policies include refusing payment altogether (this is the most common policy), payment determinations on a case-by-case basis, payment only for certain clinical indications (e.g., diseases of the central nervous system), payment for either MRI or CT scans (not both) per episode of illness, and routine payment at a variety of levels ranging up to "close to full charge." The Stason and Localio report prepared for BC/BSA concludes that, "It is premature to accept MRI as a standard, clinically effective diagnostic technique, even for general applications to the central nervous system" (Stason and Localio, 1985, p. 81). It is not yet clear how BC/BSA will respond to the report, what recommendation it will make to its member plans, and how they will respond.

The limited available data suggest that many state Medicaid agencies have not yet determined a reimbursement policy for MRI. Our provider survey indicates that Medicaid has begun to reimburse for MRI in at least a few states. The Office of Health Technology Assessment (OHTA) in the National Center for Health Services Research of the Public Health Service acts in an advisory role to HCFA on Medicare reimbursement policy. A report containing OHTA's assessment of MRI was in the final stages of preparation in late August, 1985, and was expected to be soon submitted to HCFA (Feigenbaum, 1985). HCFA is not expected to reach a coverage decision on MRI during 1985. In addition, there is no indication as yet that the Prospective Payment Assessment Commission (ProPAC), responsible for adjusting the DRG classification system every four years, has determined how it will account for the impact of MRI in its calculations.

Interviews with providers suggest that, in the absence of a decision by HCFA, the individual Medicare contractors have begun to set policy for MRI payment on their own, with some choosing to accept MR claims. The loose coordination of technology assessment activities across the Medicare system and the resulting variation in coverage policy across the nation has been well documented (Demlo, Hammons, Kuder et al., 1984).

Aggregate Impact on Health Care Costs

The net impact of MRI technology on health care costs will depend on the total costs of MRI itself, the extent to which MRI substitutes for other diagnostic modalities, and the way in which the information generated by MRI affects patient management. The last factor is the most difficult to assess. By facilitating earlier and more accurate diagnoses, MRI may make possible earlier and more efficacious treatment, thus reducing costs. On the other hand, by detecting disease processes more effectively, MRI may induce additional use of therapeutic modalities which, though beneficial for the patient, do increase costs. Detailed assessment of such factors awaits the collection of data on the actual clinical use of MRI.

In the absence of such data, any projections of MRI's net impact are highly speculative. A crude calculation based on some plausible assumptions is included here (see Table 2-8). Although the definition of MRI's role in clinical practice is still in its

TABLE 2-8

PROJECTED IMPACT OF MRI ON HEALTH CARE COSTS

MR Scans per Year	1,500,000
Technical Fee for MR	$500
Physician Fee for MR	$150
CT Scans per Year	1,200,000
Technical Fee for CT	$250
Physician Fee for CT	$100
Substitution of MR for CT	50%
Total Annual Cost of MRI	$975,000,000
Net Incremental Cost After Excluding Substituted CT Scans	$765,000,000

Source: Stason and Localio, 1985, p. 62.

early stages, it is clear that MR technology has the potential to add hundreds of millions of dollars to the nation's health care bill.

MRI in the Clinic

Patient Characteristics

A published report on the first seven months of experience with a superconductive MR system in a university hospital (Murphy, Totty, Gado, et al., 1985) indicates that 43.6 percent of examinations were neurological (head or spine), with the remaining

56.4 percent fairly evenly divided among chest, abdomen and pelvis, heart, and musculoskeletal examinations. The Evens, Jost, and Evens (1985) survey indicates that 77 percent of examinations involved head or spine, with the remaining 23 percent distributed among the chest, heart, abdomen, pelvis and extremities. Our provider survey suggests that most installations, especially those outside of teaching institutions which are not involved in research protocols, have served primarily neurological cases so far. A number of units under the control of neurologists, neurosurgeons, or neuroradiologists essentially see neurological cases only. For a variety of technical and clinical reasons, MRI is generally considered unsuitable for use in most emergencies, and very few emergencies are seen by the typical unit. Typically 70 percent or more of the patients are examined on an elective, ambulatory basis.

Insurance coverage of patients seen by MRI centers varies from region to region and center to center. Several physicians reported that many patients (usually Medicare or Medicaid patients, but sometimes BC/BS patients as well) have been forced to forego MR examinations for which they had been referred when it became clear that they could not provide payment. One university-based physician, who expressed a strong belief in the value of MRI and the adverse consequences of withholding it in certain cases, reported that he attempts to obtain scans for referred patients who lack MR coverage by including them in funded research protocols whenever feasible.

Physician Characteristics

The amount of training necessary for a physician to understand and interpret clinical MR images is not yet well defined, partly because no one yet fully understands the complex relationship between pathologic anatomy, the MR imaging parameters, and the actual images produced by MR scanners in the clinic. In its policy statement on magnetic resonance, the American College of Radiology (ACR, 1983) states only that, "Physicians engaged in MR imaging should have a knowledge of MR imaging methods achieved through training, experience, or documented postgraduate education."

A limited number of formal fellowship positions in MRI are now offered by some teaching hospitals. However, it appears that, to date, most physicians working with MR began their involvement on an informal basis. Our provider survey suggests that the training of many physicians who provide MR services is limited to a few weeks spent visiting one or more of the research-oriented, university-based MR centers, together with attendance at an occasional conference or short course. Some physicians appear to have purchased MR scanners without having had any MR experience; one radiologist with experience in CT and ultrasound described himself as "self-trained" in MR.

Not surprisingly, it appears that most physicians who offer MR services are radiologists or neuroradiologists. Evens, Jost, and Evens (1985) report that radiologists were responsible for image interpretation in 93 percent of survey sites. Radiologists expect to assume leadership in MRI provision, just as they gained dominance from neurologists in CT scanning and have cornered a 70% market in nuclear medicine imaging (James, 1983). Some neurologists, neurosurgeons, and cardiologists have become involved as well, along with a variety of other specialists, particularly at those centers carrying out research protocols focusing on various areas of the body.

Continuing Evolution of MR Practice

The published report of the early experience of the Washington University MR group (Murphy, Totty, Gado, et al., 1985) emphasizes the fact that, at the current stage of development of MR technology, optimizing MRI practice is a continuing process which promises substantial gains in efficiency as experience increases. Several examples of physician experience leading to improved MR parameter selection for particular imaging tasks are cited. Together with periodic software and hardware updates and careful attention to scanner maintenance, these advances led to a doubling in the number of patients who can be scanned per unit time, to an average of almost nine examinations per ten hour day.

Our survey reveals a decreasing tendency for physicians to use both CT and MR on a given patient and a gradually increasing volume as the number of patient referrals and the efficiency of scanning increase with experience. One physician claimed a throughput capability of 20 neurological examinations per day. He suggested that the hardware and software systems offered by different manufacturers vary considerably in their peak achievable efficiency. We were unable to confirm or disprove this assertion.

IMPLICATIONS OF CONTINUING THE CURRENT REIMBURSEMENT SYSTEM

Before considering the impact of a modification in the physician payment system, it may be useful to consider what will happen to the use of MRI if the current system remains in place. This exercise itself must take a number of conceptual liberties, because so much about MRI remains undecided or unknown. In particular, reimbursement policies of major payors have yet to be promulgated. Therefore, one can imagine two possible scenarios, each with different reimbursement attitudes by the major insurance programs.

Under a first scenario, most major payors (Blue Cross/Blue Shield plans, Medicare, and Medicaid) agree to reimburse physicians for MRI on a fee-for-service basis, paying a substantial fraction of physician charges. If this approval comes reasonably soon, the apparent pause in the acceleration of MRI diffusion will likely prove to be temporary, and diffusion will again pick up speed. Physicians or physician groups may move to acquire MRI for a variety of reasons: demonstrated and potential clinical utility, competitive pressure from other physicians, desire to gain experience with the new technology, and a general appreciation of clever gadgetry. Physicians without resources for actual purchase of MRI equipment may insist on access from other providers.

Ultimately, however, the rate of diffusion of MRI must slow, as the potential market for the devices approaches saturation. Long term prognostication is difficult because of the possibility of major but unpredictable technological breakthroughs. However, in the short or medium term, the market for MRI devices is unlikely to be as large as that for CT scanners, for several reasons. First, the cost of an MRI installation is higher than that of a CT installation, although some manufacturers have begun to offer complete imaging center packages with multiple imaging modalities and shared computation and image display facilities, which achieve some cost savings. Second, the hospital market for such expensive devices is significantly constrained, at least in comparison to the pre-DRG era when CT first appeared.

> Two provisions central to the prospective payment legislation will restrain hospitals from purchasing equipment that is likely to increase the cost of patient care. First, the legislation provides for a decrease, as compared with historical rates of spending, in the amount of funds available for acquisition of new resources. Second, the legislation creates a built-in lag in the rate at which DRG payment rates will be adjusted (Anderson, Steinberg, 1984).

Third, free-standing facilities have taken up some of the slack, but even favorable reimbursement decisions for MRI will not change the overall societal trend towards long-term tightening of health care expenditures. Private investors may realize that free-standing MRI installations may not be as profitable over the long term as they had hoped. For comparison, it is interesting to note that the CT market approached saturation -- or at least growth slowed considerably -- within a decade from its introduction.

With widespread diffusion of MRI, geographic isolation will become less of an obstacle for patients seeking MRI, though there will still be regions, particularly rural areas, which do not have populations sufficiently large to sustain an MRI installation. Referrals for MRI will become more convenient for physicians and patients. The volume of MRI scans will likely increase considerably as Medicare, Medicaid and BC/BS patients become generally eligible. For Medicare patients, PPS will encourage use of MRI as well as other technologies in an outpatient setting, outside the episode of hospitalization (Roe, 1985; Joseph, Dehn, 1984). Even in the absence of rigorous clinical studies, increasing experience with MRI might lead to the development of consensus about some clinical indications similar to that achieved by CT following a decade of use. Increased efficiency may allow increased patient throughput, resulting in a significantly reduced cost per scan.

MR will likely be used for a wide range of patients, serving in most cases as a complement to currently available diagnostic modalities. Although there is little financial incentive to substitute MRI for other diagnostic modalities under this fee-for-service system, MRI may replace invasive or risky modalities when clinical experience justifies the change. This type of substitution may yield an improvement in the quality of patient care. But in most cases, significant impact of MRI on patient outcomes will, as in the case of CT, prove difficult to demonstrate conclusively.

As was the case with CT, the struggle among physician specialists to control the delivery of MRI services will likely be settled in favor of the radiologists. But other specialists will continue to be actively involved with some categories of patients, and some may develop referral networks sufficiently large to allow them to purchase their own machines. Early development of clinically useful MR spectroscopy may complicate matters, particularly if it does not involve tomographic imaging. MR spectroscopy may encompass an entirely new set of physician specialists.

The net impact of MRI services on the aggregate health care budget under this scenario will be substantial in absolute terms, likely reaching many hundreds of millions of dollars. However, even this sum represents a very small fraction of total health care expenditure. Liberal reimbursement for MRI may help the diagnostic imaging industry recover from its current difficulties, sustaining it for a number of years until either the next great technological advance arrives or long term trends make it clear that consolidation and contraction of the industry is unavoidable.

Under a second scenario, the current reimbursement uncertainties persist. Medicare decisions about MRI payment and capital expenditure reimbursement for hospitals in general are delayed. The Blue Cross/Blue Shield Association also delays advising its members while commercial insurers continue to pay for MRI but examine their claims more closely as volume increases. State Medicaid agencies and Medicare contractors respond in a variety of ways, with the number of intermediaries paying for MRI increasing slowly as public awareness of and individual physician demand for the procedure increase. Some intermediaries in more "activist" states attempt to hold the line against MRI reimbursement as long as the situation remains unsettled.

Given these uncertainties, MRI diffusion will likely continue, but at an increasingly slower rate. Hospitals and free-standing centers will move quickly to try to establish referral networks of paying patients, but in some areas, the presence of multiple MRI installations will result in direct competition for patients. In some cases this may be sufficiently severe to exert downward pressure on MRI charges. Distribution of MRI units will be patchy, as potential purchasers carefully scrutinize the local reimbursement environment before committing themselves. Poorly-funded publicly-owned hospitals face extreme difficulty acquiring MR installations. Incentives for use of MR scanners on a outpatient basis persist, but private investors, wary of the continuing uncertainty surrounding reimbursement, may lose some of their enthusiasm for MRI.

The volume of MRI scans will likely increase gradually as more indications for its use are demonstrated and as various payors decide that they do not have the expertise or the resources to mount a strong case for denying payment. Also, the current competitive environment may encourage plans covering glamorous, "high-tech" services, such as heart transplants and MRI. Clinical applications of MRI will probably expand gradually from the present core of generally accepted neurological indications. Many patients will forego recommended MRI scans because of lack of insurance coverage; some may pay for the service themselves. Medicare and Medicaid patients will, however, be poorly equipped to do so. Some patients may undergo risky procedures which could have been replaced by MR, although the extent of this problem is as yet difficult to project. Aside from this, the impact on quality of care will be difficult to assess. In most cases, at least, people will not be substantially worse off than they are now, as they will continue to have access to whatever is currently available to them. In a few instances, however, investment in MRI may draw resources away from other services which may have benefitted those who cannot take advantage of MRI. One particular possibility is that MRI may draw research funds away from its closest competitor, CT. If this happens, CT may never reach its fullest potential.

Net expenditure on MRI services will no doubt be somewhat lower than would be expected should MRI reimbursement be assured as in the first scenario. However, even those units already installed represent an aggregate investment of several hundred million dollars. There will be continuing strong incentive for physicians to find as many paying patients as possible in order to pay for the investment.

This scenario represents the most difficult situation for manufacturers of MRI equipment. A liberal reimbursement environment could prove quite profitable; a definitive decision against MRI reimbursement would force many manufacturers to absorb significant losses, but would at least provide a timely signal that resources could be better invested elsewhere. This scenario, however, is both uncertain and volatile, making intelligent planning for future investment quite difficult. The smaller manufacturers face special problems: they must continue to make significant investments in research and development in order to have competitive product lines, but they lack the large capital resources which would allow them to absorb the large losses which would ensue if the reimbursement environment becomes less favorable after a long period of uncertainty. The longer difficult but uncertain market conditions persist, the less likely it is that MRI will be able to lift the diagnostic imaging industry back onto a high-growth path even if a favorable coverage structure ultimately develops. The bottom line, of course, is that some measure of profitability is necessary in order to sustain substantial long-term research. The MR experience, in which companies face significant risks for reasons having nothing to do with the quality of their products and their marketing efforts, could have a dampening effect on investment in medical equipment research in general.

Finally, a number of factors could have major effects on both of these general scenarios. First, the specific fee levels set by various payors, the relationship of these fees to actual MRI costs, and differences among the fees set by various payors could have a major effect on the diffusion of MRI, on the ultimate distribution of installed units, and on which patients have access to MRI for which clinical indications. Once any of the major payors adopt a liberal reimbursement policy, it will probably prove next to impossible for the others to resist pressures for payment. The lack of a coherent, well-motivated, methodologically defensible process for making coverage decisions leaves payors vulnerable to litigation by patients and providers who can draw analogies between MRI and covered procedures such as CT.

Second, decisions on capital reimbursement for hospitals under Medicare and on revision of the DRG system to account for technological advances will affect hospital demand for MRI equipment, the balance between inpatient and outpatient use of MRI, and the specific indications for which patients receive MRI scans. Third, continuing increases in HMO enrollment, including moves by Medicare to enroll substantial numbers of its beneficiaries in prepaid plans, could dampen demand for many expensive medical technologies, at least by comparison to a liberal fee-for-service environment (Iglehart, 1985; Iglehart, 1984). Fourth, breakthroughs in research could affect the economics and clinical utility of MRI in unexpected ways.

Finally, developments in the U.S. economy as a whole will strongly affect the market for MRI in both general and specific ways. A major recession, for example, could result in strong pressure by companies on commercial insurers and Blue Cross/Blue Shield to adopt more stringent cost controls. Reforms in the federal tax code[5] could profoundly affect the profitability of free-standing MRI centers and the environment in which MRI manufacturers must operate.

FOOTNOTES

1. In the public's mind, the term "nuclear" often has undesirable implications (Taveras, 1983). However, some observers feel that a "turf war" between radiologists and nuclear medicine specialists is providing the impetus for this name change (AHA, 1985). Turf battles among physicians for control of MRI may become important in reimbursement reform (see Chapter 3).
2. The unit of measurement of magnetic field strength is the tesla (T), where one T equals 10,000 gauss. For comparison, the earth's magnetic field strength is approximately one half gauss.
3. Although in utero diagnosis is one of the anticipated applications of MRI, current recommendations caution that safety in pregnancy has not yet been firmly established.
4. An alternative mechanism for bringing a new device to market, the "product development protocol," has not been elected by any MRI manufacturer to date.
5. Certain aspects of the current federal tax code are particularly pertinent to acquisition of MRI units. Non-profit health care institutions can take advantage of a variety of arrangements under which equipment such as MRI scanners is leased at favorable rates from private investors who in turn benefit from investment- and depreciation-related

tax deductions. These deductions were significantly affected by the Economic Recovery Tax Act of 1981 (ERTA), which introduced a new system under which taxpayers can deduct the cost of depreciable property over a period of time shorter than the useful life of the property. This Accelerated Cost Recovery System (ACRS) was accompanied by more generous investment tax credits (ITC). The net effect of these changes was to make private investment in capital assets such as MRI equipment more attractive. The details of the tax code affecting leasing, ACRS and ITC have been changed a number of times since 1981, most notably by the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) and the Deficit Reduction Act of 1984. These frequent changes have contributed to the volatility of the environment in which manufacturers of MRI equipment and providers of MRI services must operate.

CHAPTER 3

USE OF MRI UNDER FOUR DIFFERENT PHYSICIAN PAYMENT OPTIONS

GENERAL CONSIDERATIONS

This chapter offers speculation about the use of MRI under four physician payment reform options. The term "speculation" must be emphasized from two perspectives. First, MRI is a new technology, and, as with any other new technology, its benefits are largely unknown and its uses are continually changing and expanding. Second, there are few experiments in physician payment manipulation from which one can extrapolate to predict responses under the reform options. Therefore, at the outset it is important to stress aspects of MRI in specific and expensive technology in general which may affect physician behavior under all four options.

Issues specific to MRI are as follows:

- Limited experience. MRI is a brand new technology, with little reimbursement history. However, just as the diagnostic powers of MRI are compared with those of CT, so too the fees of the two technologies are compared. Physicians appear to feel that fees for MRI should at least match if not exceed those for CT. Historically this has been the general approach towards new technologies: new techniques are reimbursed at higher levels than old, comparable modalities.

- Availability of MRI. MRI machines are not yet widely dispersed. Because of the huge initial capital outlays required, potential purchasers may proceed cautiously. Until Part A capital payment policies are clarified under Medicare's PPS, hospitals may hesitate to make such large investments. Whether or not such purchases will continue to be attractive to non-hospital physician cooperatives or free-standing diagnostic imaging centers may depend upon expected tax code reform. Thus, supply and demand forces may play an important role in price-setting for non-Medicare patients.
- Differential costs of MRI equipment. Different MRI machines and installations vary considerably in cost. Differing patterns of incentives influencing the use of MRI can result depending on whether or not reimbursement policies take this variation into account.
- Physician qualifications. There are few physicians explicitly trained in the clinical applications of MRI. Criteria for such training have not been formalized, and many physicians appear to be learning

by performing MRI and comparing the results with those of other standard tests. Preliminary evidence suggests substantial improvements in efficiency as one progresses along the learning curve (Murphy, Totty, Gado, et al., 1985). This should potentially result in cost savings.

- Quality of scans. Not all MRI scans of the same organ are equally valuable and informative. By performing multiple scans, manipulating pulse sequences and relaxation parameters, one can obtain a wealth of data. But this process takes time. The manipulations can be minimized to provide scans more quickly. Sometimes the information sought may not appear on the quick version of the scan, and the patient may receive a second MRI scan.
- Types of scans. All scans are not alike. Scans in different organ systems may require different scanning procedures, and thus generate different costs. For example, cardiac scans require ECG gating and breast scans require specialized surface coils. Thus, the detail of the procedural coding terminology and the extent to which payors permit different reimbursement for different procedural codes become important considerations in the design of a payment system.

- Setting of service. On clinical grounds, MRI has generally been used on an ambulatory, non-emergency basis. Medicare's hospital DRG system reinforces this tendency; each option for physician payment will contribute its own set of influences to the balance of considerations affecting the setting in which the service is delivered.
- Technologic advances, clinical evidence. MRI technology is currently in a state of continual flux, as new uses are explored and older uses confirmed through additional clinical experience. Should a technologic breakthrough or research discovery prove MRI to be a cost-effective substitute for other extant technologies, this will considerably influence use of MRI.

A number of additional themes not specific to MRI also recur in considering the four payment options. First, physicians do not respond solely to pecuniary incentives. Such factors as physician age, level and type of training, professional pride, local practice customs and standards of care, academic affiliation, teaching responsibilities, patient requests, and research interests influence use of specialized services (Lowenstein, Iezzoni, Moskowitz, 1985). Diagnostic test ordering is particularly influenced by a physician's tolerance of uncertainty (Allman, Steinberg, Keruly, et al., 1985; Reuben, 1984). In addition, both physicians and the public appear to be irresistibly drawn to "high-tech" services: "as technology becomes available, there is an ineluctable dynamic that makes it intolerable to have the technology and not use it" (Richards, 1984). However, since this chapter is about reimbursement reform, the ensuing discussion focuses mainly on financial incentives.

Second, chief among financial concerns are the basic questions: how much will an individual physician receive for performing a service and will this amount permit a profit? The answer may vary according to the type of provider. As with other radiologic procedures, the fees sought by MRI providers may be expressed as a single amount, or as separate fees for "technical" (actual performance of the scan) and "interpretive" or "professional" (evaluation of scan results) services. For example, a free-standing radiologic unit owned by the physicians who operate it may charge a single combined fee for its services, while scans provided by a hospital may result in separate bills from the hospital (technical fee) and the physician who interprets the scan (professional fee). In the latter case, hospitals and physicians may face differing incentives depending on the amounts of their respective components of the fee.

Third, the impact of Medicare reimbursement reform on access to services for Medicare beneficiaries will depend partially on the response of other insurers. In turn, the competitive disadvantage for Medicare patients should other insurers prove more generous, may depend upon how many patients with other insurance reside in a given market area. If there are enough high-paying patients to fill the schedules of local MRI providers, for example, Medicare patients may face a significant disadvantage. However, if there are enough high-paying patients to cover an installation's fixed costs but not to fill its entire schedule, providers may be willing to provide scans to Medicare beneficiaries at reduced rates. This situation may be complicated by Medicare policies on assignment and balance billing. If Medicare beneficiaries can be asked to pay more than the Medicare-allowable fee, those individuals who could afford the service would obviously face fewer impediments to access than those who could not.

Fourth, the entire issue of access raises the concern about quality of care. In this sense, MRI is no different from any other new technology with as yet unproven impact on patient outcome. It is not at all clear that the health of Medicare patients will suffer if they are deprived of MRI scans. But because the diagnostic applications of MRI and the capabilities of other therapeutic technologies are presumably increasing, the present situation may change: MRI may at some point become an invaluable tool in the management of certain patients. In the meantime, two general remarks are relevant. If MRI becomes a widely used modality, it may become the accepted standard of practice without proper evaluation of its role in patient care. This appears to have been the case with CT scanners:

> The development and diffusion of CT scanners took place without formal and detailed proof of their safety and efficacy. The evidence existing today did not come from well-designed, prospective clinical trials, but from analyses of clinical experience. However, this evidence is restricted almost entirely to assessing diagnostic accuracy and usefulness, and gives little indication of the effects of CT scanning on therapy planning or on patient outcome (Banta, 1980, p. 263).

Once a technology reaches this stage of widespread use, the public and even the medical community perceive it as an essential adjunct to good quality care:

> So entrenched has the activity become that it takes rare courage for any individual or group even to question its effectiveness or desirability. To do so... is to invite retaliation from professional organizational interests, public indignation, and even in rare cases sanctions from the state (McKinlay, 1981, p. 385).

Therefore, the public and the profession may perceive MRI to be part of good medical practice without any formal proof of its favorable impact on patient outcome. Next, if one assumes that, in effect, there is a total cap on Medicare expenditures, then any investment in an expensive technology such as MRI may come at the expense of another service (e.g., preventive care). In an indirect way, this substitution may have a negative impact on quality of care.

Fifth, as with any other new technology, MRI is in a state of flux. At any time new or cost-effective uses of the technology could be identified. Therefore, the ability of the payment methodology to incorporate such changes is clearly important: with what ease can reimbursement rates be recalibrated?

Finally, as the technology advances, presumably the impact on quality of care and efficiency will increase. As with other new technologies, research and development (R&D) of MRI is proceeding on a number of fronts. R&D for both innovative hardware and clinical applications is an expensive pursuit. Funding is typically provided by grants from manufacturers, NIH, and private foundations supporting biomedical research. An additional type of "research," the uncontrolled "clinical experience" that fuels enthusiasm for a new technology, is directly funded, at least in part, by patient care revenues, although in general it is the stated policy of third party payors (including Medicare) not to support R&D on new technologies and procedures. If fees from most payors are too low to support use of MRI equipment, the research represented by the acquisition of clinical experience will be slowed. The bottom line for any industry is that some profit is required to sustain substantial long-term research. The market for MRI equipment will be severely restricted if reimbursement by major payors is insufficient to cover the cost of the equipment. Accordingly, a somewhat restrictive payment level may result in increased efforts to develop more efficient scanning algorithms and cheaper hardware, in order to preserve the viability of MRI. However, a very restrictive payment level may jeopardize the viability of the entire industry and make any further investment in R&D by manufacturers imprudent. It is difficult to predict the specific effects of changes in Medicare policy on R&D for any technology because of the complex interactions between Medicare's actions and the responses of other payors, of providers and of patients. It is possible that in the absence of strong support for MRI from Medicare, other groups would willingly pay for MRI research. For example, if in utero surgery becomes an important practice, then prenatal diagnosis using the technique of MRI (which spares the use of ionizing radiation) may become an invaluable clinical tool. Private individuals or groups fighting birth defects may actively support this R&D. Advances in MRI achieved in this way may carry over to benefit the elderly. Thus the R&D future of MRI will be affected mainly by a composite picture of how all payors respond to new applications and by the extent of private and governmental research support.

TYPES OF PHYSICIANS USING MRI

Since this report focuses on physician payment, it is also important at the outset to look at the types of physicians performing MRI and at the financial factors which motivate different groups of physicians. To the extent that profit is available, different specialists (e.g., radiologists, neurologists, neurosurgeons, cardiologists) may perform MRI scans. However, physicians presumably wish to match their opportunity costs (i.e., what they would ordinarily earn from the best alternative use of their time). Thus, a radiologist may wish to receive pay comparable to that for interpreting a CT scan; cardiologists may wish fees at least commensurate with fees for interpretation of an echocardiogram. Variations in reimbursement among different payors and among different regions may combine with similar variations in the opportunity costs of different specialists to yield a mix of specialists performing MRI which differs from region to region.

Certain specialists may be in a better position to cross-subsidize low-paying Medicare patients with other higher-paying patients. For example, cardiologists serving many middle-aged, middle-class individuals may use these revenues to counter-balance Medicare shortfalls. However, a neurologist with a large caseload of elderly patients with strokes and degenerative nervous system illnesses may not have that opportunity. In addition, certain specialists may be better able to offer "package deals" to entice patients and compete with other providers. For example, cardiologists could offer the convenience of "one-stop" echocardiogram plus MRI, while free-standing radiology groups could promote specials on joint CT and MRI scans. These groups could market these services not only by the convenience but also by the enhanced "quality" afforded by joint study of results from "complementary" modalities.

Physicians having a financial stake in the MRI facility may be most likely to order MRI scans. The accelerated cost recovery provisions of current tax law make MRI an attractive investment for physician investors of any specialty (Lundy, 1984). One study suggests that non-radiologists with an economic interest in radiologic equipment use more diagnostic x-rays than other physicians, although their choices of examination methods betray lesser knowledge of radiology than that of radiologists (Childs, Hunter, 1972). Because of this concern about excessive use of MRI scans by those who own the equipment, Medicare must decide whether or not it should pay a lower sum for such scans -- presumably creating a pecuniary disincentive for inappropriate use. This concern is probably valid, but the correct solution is elusive. Before deciding on this issue, other policies must be finalized, particularly those on assignment and balance billing. For example, if balance billing is permitted, patients who obtain scans from MRI owners may be penalized. But it would be unlikely that these patients would even be aware of the ownership issue and its attendant costs. In addition, it is improbable that a patient would question the setting of a radiologic service suggested by his or her physician. Furthermore, physicians do not respond solely to financial incentives. Physicians who own MRI equipment may be very proud of their technology and more than willing to display its imaging prowess to their peers. With such other motivations, these physicians may not be terribly troubled by a slightly lower Medicare fee. Therefore, it may be more appropriate to delegate this issue to PRO oversight, rather than relying on reimbursement control.

Finally, what impact will incentives facing those physicians who actually perform MRI scans have on physicians who do not perform MRI but may order it (e.g., general practitioners)? The answer will differ by the payment option. For example, under fee-for-service, MRI scans represent essentially "free goods" for the physician ordering them -- the MRI specialist bills separately for his service; this fee does not impinge on payment of the ordering physician. This situation may change under some of the "packaging" plans in which physicians must share single, global fees (see discussion below). But a number of general observations are pertinent. Our survey (Appendix A) indicates that some MRI providers are actively marketing their services to local physicians, by appearing at Grand Rounds, local medical association meetings, and so on. Presumably pecuniary incentives may influence the intensity of marketing efforts. Physicians who participate in local organized medical activities are more likely to be exposed to such marketing and thus perhaps more likely to order MRI. In addition, physicians who systematically scan the medical literature to keep abreast of new developments may be more likely to know about MRI and thus order it. Younger physicians, fresh out of training, and physicians in certain specialties (e.g., neurology) may also be more likely to know about MRI and thus use it. Therefore, for those physicians who do not directly perform MRI, clinical issues and the non-pecuniary factors listed in the previous section will probably be the chief motivators for use of MRI.

OPTION 1: MODIFICATION OF CPR PAYMENT

The first physician payment alternative entails a modification in the process by which physician fees are currently set -- the "customary, prevailing and reasonable" (CPR) methodology. Medicare's CPR system currently operates as follows:

> For covered services, Medicare pays 80 percent of the allowable charge subject to a deductible amount of $75 a year. The allowable charge is the lowest one of these three: (1) the physician's actual charge, (2) the physician's customary charge for the procedure (his or her median historical charge), or (3) the prevailing charge. Until 1975 the prevailing charge, which increasingly determines what the allowable charge will be, was simply defined as the 75th percentile of customary charges 'for the same service.' Since 1975, the rate at which the prevailing charge can increase has been limited to the rate of increase in the Medicare Economic Index, which reflects the physician's cost of doing business (Jencks, Dobson, 1985).

The system is complicated by regional variations in the definition of "the same service" and of the groups within which physicians' charges are compared.

Physicians may submit a bill directly to Medicare, thereby agreeing to accept Medicare's allowable charge as their total charge ("accepting assignment"). Alternatively, they may bill the patient, in which case the patient is responsible for any part of the physician's bill that exceeds the allowable charge, in addition to the deductible and coinsurance. Physicians may make this decision on a case-by-case basis, or they may become Medicare participating physicians, agreeing to accept assignment for all services for a given year.

Modification of the CPR system could follow several different strategies, oriented toward two major goals: (1) defining new fees which are cheaper than those which would have applied under the old CPR system; and (2) increasing uniformity of payment levels across physician specialties, service setttings (i.e., ambulatory vs. inpatient), and regions. To accomplish the first goal, efforts focus on such approaches as lowering the percentile at which the prevailing charge is calculated or allowing less frequent updates of prevailing charge limits. The second goal requires such actions as limiting the differences in allowable fees between specialists and generalists performing an identical procedure. Under all strategies encompassed by this first payment option, physicians continue to bill as they always have, seeking compensation for each individual itemized service.

Because of this, the detail of the procedural coding terminology upon which reimbursement is based is of fundamental importance. The American Medical Association's Physicians' Current Procedural Terminology offers six MRI codes: Code 70550 for MRI of the brain; Code 70552 for MRI of the brainstem: Code 71550 for MRI of the chest (e.g., for evaluation of hilar and mediastinal lymphadenopathy); Code 72140 for MRI of the spinal cord; Code 75552 for MRI of the heart; and Code 76400 for MRI of the bone marrow blood supply (Clauser, Fanta, Finkel et al., 1985). Note that these codes recognize only a limited number of the many potential applications of MRI. They also do not refer explicitly to several factors which could in principle be taken into account in defining the nature and value of a "service": who provides the service (e.g., specialist or generalist, which specialist)? Where is the service provided (e.g., large city, small city, rural area)? In what clinical setting is the service provided (e.g., inpatient or outpatient, hospital or free-standing imaging facility)? Which equipment was used to provide the service (e.g., a low cost resistive magnet system, a high cost superconductive magnet installation)?

The use of MRI in Medicare beneficiaries will depend heavily upon the level of the fee and the margin of profit. If fees are low, allowing no profit, MRI units would avoid elderly patients. An exception may be made for certain patients with specific conditions which are the target of a research protocol (e.g., one Boston institution is scanning all patients with newly-diagnosed sarcoma). But in this case, access would be sporadic, and scans may not be oriented specifically toward benefiting individual patients. Our phone survey (see Appendix A) found that this scenario, in which non-paying Medicare patients are avoided, is actually current policy in some areas. There is evidence for other services, that providers tend to preferentially treat patients with private, higher-paying insurers when Medicare and Medicaid reimbursement levels are low (Holahan, Hadley, Scanlan, et al., 1979).

If other payors are more generous, access for Medicare patients may depend upon lengths of queues of other patients. If scanning appointments are freely available, Medicare profit may be preferable to no profit. For those scans which are ambulatory, the access for Medicare patients may also be related to local transportation availability and the location of the MRI unit. Patients living far from the MRI installation, the poor without cars, those without friends or relatives to drive them, and persons living in regions with inadequate mass transit systems will be particularly deprived. This will be an even greater problem if those less-profitable Medicare patients are scheduled for those less-desirable after-hour MRI scans.[1]

To the extent that profit is available, multiple specialists will continue pursuit of MRI. However, as mentioned above, different specialists in different regions may have different opportunity costs they need to cover. A uniform Medicare fee may differentially affect these multiple specialists. Therefore, the mix of specialists performing MRI may differ somewhat from region to region.

Since this option maintains the traditional fee-for-service system, there is virtually no pecuniary incentive to substitute MRI for other imaging modalities. Clinical concerns may motivate such a switch (e.g., in a patient who previously had an anaphylactic reaction to the intravenous contrast agents of a competing modality). Peer pressure may prompt primary care providers to strive for cost-effective patient management. But the most probable outcome is that patients will receive all the services previously considered necessary -- plus MRI. In this sense, quality of care will be at least the same as it was prior to MRI.[2] As stated above, the impact of MRI itself on quality of care is as yet uncertain.

OPTION 2: FEE SCHEDULES

The second option involves use of fee schedules to reimburse physicians for specified services. Under this approach, physicians would receive the established fee for a certain service, regardless of their submitted charges (lower bills would be paid as submitted). The fee would be uniform from physician to physician and region to region. The fee could be set by examining the relative value (RV) of each specified service or procedure. Determination of the RV could be accomplished using several different methodologies, each with a different emphasis and each creating different incentives. For example, current charges could form the foundation of an RV scale (RVS); this RVS would preserve the inequities of the present system. Another methodology could focus on the resources required to perform a service; given this emphasis, procedural and cognitive services would presumably have the same margin of profit. This would engender financial neutrality about which type of service to provide. Finally, another methodology could be more purposeful, setting profit margins specifically to encourage performance of certain types of services which are deemed to be preferable to others. Obviously, the type of RVS selected will have substantial impact on the use of all types of services.

Because the "value" of a clinical service is necessarily subjective, the process of defining an RVS would be of major importance. The choice of the particular individuals or organizations who will define the RVS, and the particular conception of value that is settled upon, may be the focus of controversy. It is certain that practicing physicians, both individually and through medical societies, will seek to influence the process in order to protect their perceived interests; as an RVS may involve tradeoffs among different types of services, conflict may arise within the medical profession as well.

If RVS fees are set to allow at least a modicum of profit, use of MRI among the elderly shall certainly increase. Changes in the profit margin across different services caused by the RVS methodology (i.e., a surgical procedure may now be equally lucrative as a non-invasive service) may cause some shift in the relative popularity of a service. If non-invasive imaging services such as MRI are treated more generously than others, then there may be a disproportionate shift toward the relatively more lucrative service. The extent of regional uniformity imposed on MRI fees may also influence its use. Rural areas may have disproportionately low siting costs but may not have a large enough population base to adequately support a fixed MRI installation. This may create relatively high average costs which may not be adequately covered by a uniform fee. A mobile unit offers one solution, but these units can actually be quite expensive. Urban areas and particularly expensive specialists in tertiary teaching institutions may also suffer a loss from a uniform fee schedule. Thus, the incentives for use of MRI may vary from region to region.

The opportunity for profit will continue to attract a range of specialists. A fee schedule which imposes a uniform fee across specialties may alter the relative profitability of MRI in different specialties (depending on different opportunity costs in different specialties). The mix of specialists may vary by region. High-priced urban cardiologists or neurosurgeons may not find it worth their while to perform MRI scans, relegating this task to less expensive local radiologists or other specialists. Decreasing financial rewards for MRI may lead specialists trained specifically in this technique to perform more scans to maintain their target income (Jencks, Dobson, 1985).

This option perpetuates the traditional fee-for-service system, merely recalibrating the amount of the fee. If the relative profit margins of the current CPR system are continued, there would be little incentive to substitute MRI for another service which offers similar clinical information and a profit: the incentive remains to do both. However, a relevant consideration here is not just the absolute fee level, but the relative profitability of MRI compared to that of competing technologies. Any system of payment by fees offers the opportunity to create incentives for use of one technology over another by modifying its relative price. For example, given a goal of substituting MRI for myelography (a modality which requires injecting a contrast agent into the cerebrospinal fluid to determine whether any structures or masses are impinging on the spinal cord; in many hospitals it demands an overnight hospital stay), prices could be set to allow a large profit margin for MRI and only a slim margin for myelography. This approach would clearly shift preference away from myelography toward MRI. To the extent that the RVS encourages substitution of MRI for more invasive risky procedures in the future, this payment strategy could improve overall quality of care. It may also shift preference toward MRI for the many situations where it is not necessary.

However, as stated above, it is premature to discuss substitutions of this technology for any others. In those areas of consensus about the clear superiority of MRI — scanning of the posterior fossa and the cervical spine -- there are no truly comparable competitors. But an important aspect of an RVS methodology is whether it can respond to these developments as they occur. One possibility is that, when the technology has little proven value, its reimbursement could be low. But once true benefits are determined, higher profits could be allowed. Another possibility is the setting of a "temporary" fee which is periodically recalibrated according to an evaluation of knowledge about the technology. However, these concepts may be based on a faulty assumption: true benefits may never be accurately known.

OPTION 3: PACKAGING

The third option involves reimbursement by "packages" of services. Potential packaging approaches can be arrayed along a continuum. At one extreme, individual services or procedures with necessary associated ancillaries would be considered separate packages; this end of the continuum closely mimics the current definition of service. At the other extreme are episode of care packages; these packages incorporate all services, both inpatient and outpatient, required in managing a specific episode of illness. In between these two extremes are a variety of levels of aggregation including ambulatory care packages and hospital-based packages paralleling the current hospital DRG methodology (i.e., physician DRGs). Under Option 3, a pre-specified total sum would be allocated to compensate for all physician contributions to a given package. The exact mode of distributing the lump sum to all participating physicians is unspecified.

Technically, Option 3 perpetuates a fee-for-service system -- the nature of the service has merely been restructured. However, depending upon the level of aggregation of the packages, this option could substantially alter the pecuniary incentives for use of individual services. As a diagnostic service which must be performed by a specialist and which, to date, has been shown to make only marginal clinical contributions when added to competing imaging modalities, MRI is particularly vulnerable under Option 3.

MRI, in many cases, may be considered dispensable if it would rob reimbursement from other time-honored and standard diagnostic approaches.

The use of MRI under a packaging system would be influenced by the same factors noted in the discussions of Options 1 and 2: definition of the service, payment for and cost of providing the service in question, payment for and cost of providing other services, response of other payors, and demand for the service. However, the situation is complicated by the added factor of aggregation of multiple "services" into "packages," and the resulting necessity to divide the package fee into payments for the contributing providers. Devising a suitable division, though difficult, can be done beforehand when the package is made up of a constant set of services (e.g., "package" = "initial consultation with generalist" + "MRI scan" + "interpretive service by radiologist"). However, when the package is defined only in general terms, so that the specific services delivered may vary from case to case (e.g., "package" = "all services needed during an episode of illness"), the payor or its designated intermediary or "case manager" may be faced with the necessity of determining the division of fees on a case-by-case basis.

Timing of patient assignment to packages must also be considered in package design. Assigning patients to a particular package because of results of a diagnostic test may result in increased use of that test. Conversely, patients could not be pre-assigned to a package defined by final diagnosis if the diagnosis is not known until the diagnostic technologies are already used. This is a concern about the current hospital DRG system. Under this system, DRG assignment is based upon the principal reason for admission. However, diagnosis is not always known at admission. For example, an elderly patient may be hospitalized with a "diagnosis" of mental status changes which could be precipitated by a number of processes (e.g., tumor, infection, stroke, metabolic derangement). The exact cause will not be known until the appropriate tests are performed. It is not clear how hospitals are dealing with this problem (Iezzoni, Moskowitz, 1985).[3]

In many cases, MRI may be used either to confirm a diagnosis suspected clinically or to evaluate the extent of a known process (e.g., extent of tumor metastatic to the brain). In these instances, a packaging definition based on diagnosis would be appropriate. Other cases involving work-up of a symptom of unknown etiology present a more challenging definitional problem. One could presumably create packages such as, "Evaluation of Central Nervous System Disorder," which would ultimately yield a broad range of diagnoses but through similar work-ups (e.g., most patients would receive lumbar punctures, CT scans, and MRI scans). Packages could be created explicitly for MRI: there is a precedent for this type of DRG; DRG 412, "History of Malignancy with Endoscopy," is a medical DRG in the current list. More empirical evidence on practice patterns and costs is needed before a final decision on the appropriate package definition strategy.

In any case, packaged reimbursement would foster use of the cheapest possible MRI scan: one with minimal manipulation of the scanning parameters and thus perhaps yielding a bare minimum of clinical information. It is not clear what the potential impact of these scans of marginal quality may be. It is possible that the results of such scans could be misinterpreted or over-interpreted because of absence of information which would have been produced by a more complete scanning process.

If setting of care is encompassed by the packaging methodology (e.g., package is specifically for hospital care only; package is for both hospital and ambulatory care), this could influence use of MRI among the elderly. If packages exclude ambulatory care services and provide adequate compensation for procedures performed in the outpatient setting, use of MRI would burgeon in this context. Total episode packages would yield the greatest disincentive to both inpatient and ambulatory use.

By nature Option 3 puts physicians at odds -- all physicians must vie for a portion of the package pie. Turf battles over control of MRI may increase in significance in this context. Radiologists would be at a particular disadvantage because radiologists must always be consultants (i.e., radiologists do not admit patients to the hospital or serve as attending physicians). However, neurologists, neurosurgeons, and cardiologists can both perform and interpret MRI scans and function as attending physicians. Given the choice between doing an MRI scan himself or asking a radiologist to perform the scan and share the fee, one of these clinial specialists will obviously prefer the former route. MRI scanners may therefore spring up in different departments throughout the hospital or community (to the extent that fees are set high enough to permit profit on the packages sponsored by those departments). Thus, the extent to which physician specialists can both serve as providers of MRI and as primary attendings may determine the mix of physicians performing MRI.

In this case, creative marketing strategies could lure some MRI business into the radiologists' camp -- especially from those general physicians not specifically trained in MRI techniques. One example involves specials on imaging services. Physicians would refer their patients to imaging units without specifying which exact modality should be used. The radiologist, after reviewing the patient's history, would select the imaging approach which he believes is most cost-effective and clinically suitable. The fee sharing arrangement could be previously arranged, so that the proportion of the package sum going to the radiologist would be constant and predictable regardless of the choice of imaging modality. Such an arrangement would require trusting and good collegial relationships. The referring general physician must be satisfied that the patient's best interests were met. General medical doctors may be more willing to send their patients to radiologists than to other clinical specialists for their MRI scans. They may be afraid that the specialist (e.g., a cardiologist) may either usurp the attending role or may actually be preferred by the patient due to his demonstrated additional skills.

This entire discussion is predicated upon the assumption that the group of physicians providing the packaged services will be clearly involved in the sharing the fee (e.g., through a gatekeeper physician). However, there are other less direct reimbursement methodologies. An intermediary could dispense fees for a group of physicians. The definition of the physician group could prove quite important: does the group include radiologists? The exact dynamics of the group could have considerable bearing on the incentives about MRI which trickle down to individual practitioners.

Option 3 offers strong motivation to substitute more efficient modalities for those which are less efficient. Thus, as opposed to Options 1 and 2, Option 3 pushes toward performance of either a CT scan or an MRI scan -- not both. At this time, it is unlikely that most decisions about substitution of MRI would be made on truly substantive grounds: Information about the cost-effectiveness of MRI does not yet exist. Such decisions are more likely to be founded upon factors such as availability of MRI, the interest or enthusiasm of the attending physician regarding MRI, and the relative power that the practitioners of competing technologies have to obtain substantial portions of the package fee.

Given that MRI is a new and expensive, largely untested technology, its position is relatively weak. For the time being, it is likely to lose out to established modalities with entrenched professional constituencies. Because it is only a diagnostic technique -- not a technology such as lithotripsy or lens implants with clear therapeutic outcomes -- public demand for MRI in this reimbursement setting will also probably be somewhat reserved. Therefore, unless research on MRI proves that it is a cheaper, equally effective imaging modality, it is unlikely that MRI will soon dislodge other extant diagnostic technologies.

Option 3 also offers a worrisome incentive for under-utilization of services with potential deleterious impact on quality of care. Certainly a number of horror stories are arising about undercare abuses in Medicare's hospital prospective payment system (Freudenheim, 1985; Hull, 1985). But is is not yet clear: (1) how widespread these abuses are; and (2) how physicians specifically will respond to these incentives given their counter-incentives (e.g., professional ethics, fear of malpractice litigation). As in Options 1 and 2, there may be a public perception of lower quality care if Medicare patients are denied MRI.

The issue of substitution suggests the possible direction of R&D under Option 3: it will be oriented toward improving the relative efficiency of MRI and clearly differentiating MRI from potential competitors. These research goals are more conservative and are less likely to yield startling new discoveries than a more richly endowed research environment. But this R&D could be quite rewarding if it produces MRI processes which can successfully compete with more invasive imaging techniques (e.g., angiography).

OPTION 4: CAPITATION

Option 4 involves capitation payment for physician services: a fiscal intermediary or health plan will be paid a per capita sum for all care to program enrollees; the physicians would share these capitation fees. The exact methodology of fee distribution is unspecified, but could follow several models. For example, using a health maintenance organization (HMO) model, participating physicians would receive salaries supported by the capitation amounts (Gaus, Cooper, Hirschman, 1976). Such a salaried approach negates the pecuniary incentives for performance of individual services generated by a fee-for-service system. Case managers may be required to screen procedure and referral selections. Under such an approach, specialists providing services could continue to be reimbursed for each individual service. Incentives offered by this methodology depend on the degree of commitment of the case manager to the provision of appropriate cost-effective care. Under a regional capitation methodology, Medicare could pay a corporation to underwrite all services in a given area. The underwriter could offer a variety of alternatives, including the traditional Medicare system. The underwriter would therefore be at risk for cost overruns (Jencks, Dobson, 1985).

A capitation system discourages use of additional services because of incentives similar to those ascribed to Option 3. Only if MRI is clearly clinically indicated or is a more efficient modality than close competitors, would its use be sanctioned. This lower use would not pertain just to MRI, but may be true for many sophisticated services and procedures. One study found that HMO cardiologists are less likely to perform thallium scintigraphy, coronary angiography, and coronary artery bypass surgery than community-based specialists (Hlatky, Lee, Botvinick, et al., 1983). Thus, Medicare beneficiaries may not only receive fewer MRI scans but may also obtain fewer of the complementary technologies such as CT.

Even if Medicare beneficiaries do receive MRI scans, the setting of scan provision may be somewhat different from the setting of other options. Take the HMO as the model. New HMOs are especially wary of large capital investments (Heyssel, Seidel, 1976). Other HMOs appear to move slowly towards acquisition of expensive technologies. They closely observe the experiences of other providers with new equipment and contract out for indicated services, only making purchases once clinical utility and efficiency are well-demonstrated. For example, Kaiser-Permanente of Northern California contracted for use of a CT scanner owned by an outside organization. "Only when volume had reached the point at which the cost to buy the service exceeded the cost of producing it internally was a head scanner ordered" (Sisk, 1984). HMOs are also more likely to advocate outpatient diagnostic work-ups (Roemer, Shonick, 1973). One study demonstrated that HMOs have 40 percent lower hospitalization rates than comparable fee-for-service groups (Manning, Leibowitz, Goldberg, et al., 1984). This evidence also implies greater reliance on outpatient diagnostic services.

If Option 4 results in HMO-like provider groups, it is unlikely that such groups will move avidly towards purchase of MRI machines. More likely, these HMOs will enter into a contractual relationship with entities which own machines which are not operating at 100 percent volume. Perhaps the HMO will negotiate a special deal with these providers whereby HMO patients may be scanned at low cost if they accept after-hours slots (the MRI provider may wish to reserve the more desirable daytime appointments for higher-paying customers) or appointments scheduled only a day in advance (to fill up vacant slots which were not taken by higher-paying patients who schedule many days in advance).

The concerns outlined above translate directly into access problems for elderly patients seeking MRI. Under a case manager approach, it is unlikely that the patient would be permitted MRI "on demand." Depending on public perceptions of the utility of MRI, out-of-plan use may become a significant practice. In this case, patients who have the independent means to compensate for the service would do so; less affluent patients would be constrained to the indications specified as allowable for plan beneficiaries. In this context, Option 4 is more likely than the other options to stimulate specific lists of criteria for MRI use. Access for these specified conditions would be unrestricted, while any other use of the scans would be flatly denied. The ability of the system to incorporate new indications as they develop would clearly be important.

Most likely, Option 4 will yield lower total profits on MRI than any of the previous options. Therefore, although an incentive may persist for a full complement of specialists to compete for dominance of MRI, there may be some physicians who seek more lucrative alternatives. As in Option 3, specialists who are in a position to offer bargains on their services will most likely achieve pre-eminence in MRI provision. For example, radiologists who provide discounted, generic imaging packages would possess a distinct advantage. Other specialists may also devise package deals at special rates. For example, a cardiologist could set a single price for a package including both a cognitive consultation as well as the appropriate imaging modality from a list of potential options (e.g., MRI, echocardiography, radionuclide scan). This offer may prove more tempting than one restricted to imaging procedures alone, because of the inclusion of the cognitive component.

The specialist mix may also depend on the nature of the case manager. Obviously, it is exceedingly unlikely that a radiologist could ever serve as the case manager. If a specialist such as a neurologist or neurosurgeon, trained in MRI techniques, serves as case manager, it may be more likely that a scan would be obtained -- performed by the manager himself (either at his own scanner or at a hospital-based unit; at one of our survey sites [see Appendix A] cardiologists have full use of the hospital's scanner one afternoon a week while neurologists operate it another afternoon a week).

The system may have tighter controls on diagnostic procedures overall. For example, an order for an MRI scan may require a counter signature or note of approval from a department chairman or utilization review board. This control may be especially tight if the MRI services are contracted outside the plan. Whoever controls this approval process may also be in a position to dictate the specialist who will actually perform the scan.

Finally, in an HMO-type setting, collegial relationships may prove quite important in the actual decision to obtain a MRI scan. A number of analysts have observed that, when confronted with uncertainty, physicians in formally organized groups tend to consult their resident experts (Dorsey, 1983). If the local specialist is a particular advocate of MRI, a high rate of MRI use could be expected. It is this dependence on individual opinion in the face of clinical uncertainty which may underlie the tremendous small-area practice variations observed by Wennberg in Maine (Wennberg, 1982).

Option 4 offers the strongest incentive of all four payment methodologies for substituting more efficient techniques for those which are less efficient. However, the concerns listed for Option 3 are also relevant here. MRI is a new, expensive technology, still undergoing testing. In scanning the posterior fossa and cervical spine (the two areas which offer consensus on its superiority), it has no true competitors -- it is clearly better than CT for this application. Thus, although this is beneficial for selected patients , MRI adds to the burden of technology; it does not provide a more efficient substitute. In a system such as Option 4, in which there are serious constraints on health service provision overall, it may prove exceedingly difficult for a new technology to successfully compete against well-entrenched alternatives (e.g., CT) which offer similar clinical information. Unless a startling breakthrough clearly establishes MRI as a clinically superior or more efficient modality, substituting MRI for existing technologies is likely to be a fairly limited practice.

Critics of capitated payment systems have historically raised the specter of substandard care, citing the presumed incentive of the plan to economize at the expense of patients (Schwartz, 1978). However, this outcome has yet to be demonstrated in HMOs which have been studied (Luft, 1980; Wolinsky, 1980; Manning, Leibowitz, Goldberg, et al., 1984). In fact, quality of care may actually improve if patients are spared risky tests which offer minimal clinical gains. The interaction between MRI and this option, in relation to quality of care, depends upon the rapidity with which the system can adopt new indications for MRI which serve as substitutes for invasive procedures. If Medicare patients are then deprived of the lower risk MRI scan, quality of care will clearly be compromised.

This option offers perhaps the most constrained profit potential of all four scenarios. Any R&D pressure which might arise would certainly mimic that of Option 3 -- towards cheaper machines, more efficient scanning practices, and methods which would clearly differentiate MRI from competitors (e.g., CT). Patient care revenues would be very unlikely to support research. If more efficient units are developed, profits may increase and motivation for MRI use would likewise increase.

FOOTNOTES

1. Some respondents to our survey (see Appendix A) indicated that they intend to operate their MRI units well beyond the usual 9 to 5 hours, including late evening shifts.
2. This statement assumes that MRI is virtually a "no risk" technology. As described in Chapter 2, with a few exceptions, side effects from MRI itself appear negligible. However, in the total context of patient care, the risks of MRI include not only the risks of the MRI itself but also the risks of other technologies used because of MRI. For example, MRI, if falsely positive (the so-called "unidentified bright object" or UBO) may lead to an unnecessary biopsy with its attendant risks. This is not a problem unique to MRI; it pertains to virtually every diagnostic test which is not 100 percent accurate.
3. For years, hospitals have given ICD-9-CM diagnostic codes to suspected or uncertain conditions by following these basic rules: If the diagnosis at the time of discharge is stated as "suspected," "questionable," "likely," "?," and so forth, code the condition as if it existed or was established. If the discharge diagnosis is stated as "rule out...," it is to be interpreted as "suspected" (AHA, 1979). Note that these coding rules assume that diagnosis is determined at discharge.

CHAPTER 4

IMPLICATIONS FOR PAYMENT POLICY

Chapter 3 contained speculation about utilization of MRI under four different physician payment scenarios. Table 4-1 summarizes expected physician responses; the conditions used for these projections were selected only to provide examples of possible scenarios. Several features of MRI proved important when considering incentives for its use by physicians:

- MRI is a new, expensive technology with as yet unproven clinical utility in most areas.
- MRI has tremendous potential future benefit.
- MRI is a diagnostic, not therapeutic, modality.
- MRI has entered a field crammed with other diagnostic techniques which are already part of accepted standard medical practice, such as CT.
- MRI is generally a scheduled, non-emergency procedure.
- All MRI scans are not alike.
- All MRI machines are not alike.
- MRI must be performed by physicians specifically trained in MRI use.
- The most common specialists involved in MRI -- radiologists -- do not serve as admitting physicians.

TABLE 4-1

USE OF MRI UNDER FOUR DIFFERENT PHYSICIAN PAYMENT OPTIONS

	Option 1: Modification of CPR Payment	Option 2: Fee Schedul
Factors affecting impact of option	• Definition of service • Amount of payment • Cost of providing service • Payment for and cost of providing other imaging services (e.g., CT) • Response of other payors • Demand for MRI services • Research developments, especially breakthroughs which improve MRI efficiency • Frequency and method of recalibrating payment amount	Same as Option 1
Conditions assumed as basis of projections	Payment more restrictive than at present but still greater than average cost at typical high-volume MRI installation	Payment set very restrictively to allow profitability only for low-cost providers
Use of MRI in elderly	Increases steadily	Increases slowly
Geographic access of elderly to MRI	Increases slowly	Increases very slowly a probably unevenly
Physicians using MRI	Primarily radiologists, but some other specialists (e.g. Neurologists, cardiologists) as well	Primarily radiologists
MRI as a substitute	Little financial incentive; some substitution on clinical grounds	Probably same as Option but substitution may be encouraged by design of fee schedule
Quality of care	Difficult to assess; probably unchanged relative to quality prior to payment reform	Same as Option 1
Research and development	Continues as at present	Incentive for developme of low-cost equipment

TABLE 4-1 CONTINUED

	Option 3: Packaging	Option 4: Capitation
Factors affecting impact of option	Same as Option 1; nature of the packages very important	Design of capitation system very important, especially amount of capitation payment; response of other payors important
Conditions assumed as basis of projections	"Physician DRGs" analogous to hospital DRGs; only for inpatient services; other payors assumed unchanged	HMO-type arrangement for Medicare beneficiaries; no special response by other payors
Use of MRI in elderly	Increases slowly as clinical utility is clarified or efficiency documented	Same as Option 3
Geographic access of elderly to MRI	Access greater in outpatient setting	Same as Option 2
Physicians using MRI	Primarily radiologists, Creative marketing strategies involving all imaging services	Same as Option 3
MRI as a substitute	On those occasions when MRI is clinically indicated, substitution for other diagnostic modalities likely for reasons of cost containment	MRI used as substitute, rather than complement, whenever possible because of overall expenditure cap
Quality of care	Difficult to assess; however, incentives may favor excessive restrictions on use of all high-cost technologies, including MRI	Same as Option 3
Research and development	Restricted compared to Options 1 & 2; incentive for development of low-cost equipment and measures to improve efficiency	Same as Option 3

- Because of its high cost and limited current clinical indications, large population bases are needed to support MRI installations.
- A relatively large number of MRI units are located outside hospitals and serve mainly ambulatory populations.
- Since its potential usefulness is not limited to an elderly population, but may actually be skewed towards a younger age range (children), the impact of Medicare payment policy is hard to assess.

The analysis of Chapter 3 assumed mainly pecuniary incentives for use of MRI. But it is important to balance this discussion with consideration of those non-pecuniary incentives which drive use of medical technology. In fact, some experts argue that financial factors are of distinctly lesser import to physicians than a "technologic imperative":

> Medical tradition emphasizes giving the best care that is technically possible; the only legitimate and explicitly recognized constraint is the state of the art (Fuchs, 1968).

Even technologies with unproven benefits are preferred to doing nothing at all:

> The aim of the practitioner is not knowledge but action. Successful action is preferred, but action with very little chance for success is to be preferred over no action at all (Freidson, 1970).

One particularly troubling constant in medical practice is the limitation of medical knowledge and the profound role of uncertainty in defining diseases, making diagnoses, selecting procedures and observing outcomes (Eddy, 1984). Yet physicians must choose a course of action for each patient and clinical situation. One analyst suggested that physicians deal with this uncertainty by developing customary behaviors transmitted through clinical training, community education, and collegial relationships. This approach is contrasted with instrumental or rational behavior in which choices are based on knowledge of actual costs and benefits for particular patients, information generally lacking in the clinical setting (Temin, 1980). These professional relationships have long been acknowledged to play a major role in dissemination of new technologies (Coleman, Katz, Menzel, 1966). Peer recognition and patient satisfaction are also important motivators apart from expectation of increased future financial gain (Fuchs, 1974).

All these factors are clearly relevant to the use of MRI -- an exciting, new, and sophisticated technology. MRI fulfills the "technologic imperative," by sitting on the cutting edge of the state of the art. Even though few benefits have yet been proven, it allows a physician to act with little fear of untoward side effects from his action. As was the case with CT, its use could lead to its acceptance as a standard, customary diagnostic modality without clear documentation of its cost and effectiveness. The enthusiasm of professional colleagues for MRI may prove an important force in a local community of physicians. Peer recognition for development and use of the latest techniques is clearly important in MRI. Finally, patients may be more satisfied and impressed by use of such a sophisticated technology.

Payment policy reforms will not alter these non-pecuniary incentives. The balance between these forces and financial motivations is not clear. What may be true is that in these times of fiscal constraint, the balance may tip towards pecuniary concerns. If physicians cannot maintain a livelihood or institutions cannot afford to purchase MRI machines, all the non-pecuniary motivations may have little impact -- if MRI is not available, patients will not have it, regardless of the desires of their physicians.

Therefore, returning to the speculations of Chapter 3, the payment alternatives can be broadly arrayed along a continuum. Motivation for its use is highest in modification of the CPR system and lowest under the capitation option. What are the implications of this continuum? In considering the implications of any MRI payment policy, there are several dimensions.

First, cost is an important dimension. Any system which encourages use of MRI will probably increase total costs of the medical care system. Even strategies which foster substitutions of MRI for other modalities may ultimately result in increased net costs: it is likely that in many of its expected uses, MRI may have no true competitor. Some speculate that MRI could reduce hospitalization, surgery, and thus costs, but these benefits remain purely conjectural.

Second, favorable impact on current patient care is as yet unproven in the vast majority of cases. Given the state of current therapeutic art, it is unlikely that most patients will ultimately face improved outcomes from their exposure to MRI. In other words, if MRI were banned tomorrow, only a very limited handful of patients would probably suffer.

Third, MRI does offer an extremely exciting future. MRI could potentially replace a number of standard modalities with acknowledged risks, it could supplant invasive techniques of tissue characterization, and it could yield earlier, more precise diagnoses. It is impossible to say what effect constraint on current MRI techniques will have on the pace of future advances. Policies which foster MRI use at research institutions may appear to protect future gains, but even this is not entirely clear.

Finally, MRI does not exist in a clinical vacuum. Its utility is directly proportional to advances in the therapeutic world. MRI's diagnostic strength may contribute to treatment developments, or the early diagnosis yielded by MRI may become important in light of independent therapeutic breakthroughs. The ability of a reimbursement system to encourage therapeutic research and to accommodate new developments thus becomes obviously important.

Therefore, MRI presents a complicated picture, a composite of lack of current proven widespread benefit with a potential for tremendous future gain. Policy makers must weigh the total picture, not just a single aspect or perspective. Trade-offs of present resources for uncertain but rewarding future benefit are always difficult. Selecting a reimbursement policy for MRI will thus prove to be a complicated task, made in conditions of great uncertainty.

CHAPTER 5

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APPENDIX A

During June and July 1985, we surveyed a small group of MRI installations in order to supplement the available published data with more current information and to better understand the perspective of MRI providers. Interviews focused mainly on financial factors and clinical experiences.

We chose installations spanning a range of geographic areas, practice settings and equipment types. However, our results only identify important considerations and provide a qualitative understanding of trends in MRI practice. They do not represent a statistically valid or comprehensive summary of the aggregate MRI experience.

We are grateful to the following individuals for sharing their experiences and opinions with us as part of this survey. These persons have not reviewed our report; their participation cannot be viewed as an endorsement of our findings or perspective.

R. Ansel
Oakland Magnetic Imaging Services
Oakland, CA

T. Brady
Massachusetts General Hospital
Boston, MA

A. Carothers
Montvale Medical Imaging
Montvale, NJ

S. Devoisin
Inland Imaging Limited Partnership
Spokane, WA

A. Green
University Hospital
Boston, MA

S. Harms
Baylor University Medical Center
Dallas, TX

J. Koutcher
Massachusetts General Hospital
Boston, MA

B. Kneeland
Medical College of Wisconsin
Milwaukee, WI

W. Martel
University of Michigan
Ann Arbor, MI

J. Robins
Magnetic Resonance Center of San Diego
San Diego, CA